

# BMJ Open Motor control exercise for symptomatic lumbar disc herniation: protocol for a systematic review and meta-analysis

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## ABSTRACT

**Introduction:** Lumbar disc herniation (LDH) is a common condition in adults and can impose a heavy burden on both the individual and society. It is defined as displacement of disc components beyond the intervertebral disc space. Various conservative treatments have been recommended for the treatment of LDH and physical therapy plays a major role in the management of patients. Therapeutic exercise is effective for relieving pain and improving function in individuals with symptomatic LDH. The aim of this systematic review is to evaluate the effectiveness of motor control exercise (MCE) for symptomatic LDH.

**Methods and analysis:** We will include all clinical trial studies with a concurrent control group which evaluated the effect of MCEs in patients with symptomatic LDH. We will search PubMed, SCOPUS, PEDro, SPORTDiscus, CINAHL, CENTRAL and EMBASE with no restriction of language. Primary outcomes of this systematic review are pain intensity and functional disability and secondary outcomes are functional tests, muscle thickness, quality of life, return to work, muscle endurance and adverse events. Study selection and data extraction will be performed by two independent reviewers. The assessment of risk of bias will be implemented using the PEDro scale. Publication bias will be assessed by funnel plots, Begg's and Egger's tests. Heterogeneity will be evaluated using the I<sup>2</sup> statistic and the  $\chi^2$  test. In addition, subgroup analyses will be conducted for population and the secondary outcomes. All meta-analyses will be performed using Stata V.12 software.

**Ethics and dissemination:** No ethical concerns are predicted. The systematic review findings will be published in a peer-reviewed journal and will also be presented at national/international academic and clinical conferences.

**Trial registration number:** CRD42016038166.

## INTRODUCTION

Lumbar disc herniation (LDH) and disc protrusion are one of the most common spinal degenerative disorders, which can lead to low back pain (LBP) and radicular leg pain.<sup>1</sup> It is a pathological condition that frequently

## Strengths and limitations of this study

- This systematic review and meta-analysis will evaluate the effectiveness of motor control exercise for symptomatic lumbar disc herniation. There will be no limitation by language and grey literature will be included if identified through the searches.
- This protocol was prepared according to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) recommendations.
- Full-text screening, data extraction and risk of bias assessment of included primary studies will be conducted by two reviewers independently.
- Some relevant unpublished trials with negative findings that meet our inclusion criteria might be missed (publication bias). Therefore, funnel plots will be used to detect possible publication bias in order to reach an objective conclusion.

affects the spine in young and middle-aged adults.<sup>2</sup> This condition is defined as a displacement of disc components (nucleus pulposus or annulus fibrosus) beyond the intervertebral disc space.<sup>2–5</sup> It has been shown that LDH is the most common cause of radiculopathy (90%).<sup>6,7</sup> The highest prevalence of disc herniation is among adults aged 30–50 years, with a male to female ratio of 2:1.<sup>4</sup> In adults aged 25–55 years, about 95% of LDH predominantly occurs at the L4–5 and L5–S1 spinal levels.<sup>4</sup> Disc herniation above these levels is more common in adults aged over 55 years.<sup>4</sup> However, it has been reported that LDH is not always accompanied by clinical symptoms such as LBP (asymptomatic LDH).<sup>1</sup> Studies by Boden *et al*<sup>8</sup> and Jensen *et al*<sup>9</sup> indicated that 24–27% of asymptomatic subjects have disc herniation. In addition to the general wear and tear (degenerative joint disease) that comes with ageing, many risk factors have been reported for LDH, such as gender, weight, profession, smoking, psychosocial

factors, exposure to vibration and sedentary lifestyle.<sup>10–12</sup> The cardinal symptoms of symptomatic LDH include LBP, radicular leg pain, sensory loss (paraesthesia, numbness and tingling), muscle weakness and incontinence (rare).<sup>13</sup>

A variety of therapeutic interventions have been proposed for the treatment of symptomatic LDH, including non-invasive treatments, minimally invasive procedures and surgery.<sup>14</sup> It was demonstrated that symptomatic LDH could be effectively treated both surgically and non-surgically.<sup>15</sup> Non-invasive (non-surgical) treatments are considered to be a first-line choice for most cases.<sup>16</sup> Bed rest, physical therapy, comfortable positioning, manipulation and drug therapy (non-steroidal anti-inflammatory drugs) are the most used non-invasive treatments.<sup>17</sup>

Physical therapy programmes are often recommended for the treatment of pain and restoration of functional and neurological deficits associated with symptomatic LDH.<sup>18</sup> Active exercise therapy, which is a type of physical therapy programme, is usually preferred to passive modalities.<sup>19</sup> There are a number of exercise programmes for the treatment of symptomatic LDH, such as activity as usual, aerobic activity (eg, walking, cycling), directional preference (McKenzie approach), flexibility exercises (eg, yoga and stretching), proprioception/coordination/balance (medicine ball and wobble/tilt board), motor control and strengthening exercises.<sup>20</sup> Motor control exercises (MCEs) or stabilisation or core stability exercises are a common type of therapeutic exercise prescribed for patients with symptomatic LDH. MCEs are designed to re-educate the co-activation pattern of abdominals, paraspinals, gluteals, pelvic floor musculature and diaphragm.<sup>21 22</sup> The biological rationale for MCEs is primarily based on the idea that the stability and control of the spine are altered in patients with LBP.<sup>23 24</sup> A MCE programme begins with recognition of the natural position of the spine (mid-range between lumbar flexion and extension range of motion), considered to be the position of balance and power for improving performance in various sports.<sup>25</sup> Initial low-level sustained isometric contraction of trunk-stabilising musculature and their progressive integration into functional tasks is the requirement of MCEs.<sup>22 26</sup> MCE is usually delivered in 1:1 supervised treatment sessions and sometimes includes palpation, ultrasound imaging and/or the use of pressure biofeedback units to provide feedback on the activation of trunk musculature.<sup>27</sup>

### How the intervention might work

Control of the spine is complex and depends on well-coordinated, deep-trunk musculature. The deep-trunk musculature, which originates and inserts segmentally on lumbar vertebrae, can maintain the stiffness of the spine by controlling intersegmental motion and spinal curvature.<sup>28</sup> Hodges and Richardson<sup>29 30</sup> indicated that patients with LBP may have a delayed activity onset of

the deep-trunk musculature in dynamic tasks that challenge control of the spine. Furthermore, a reduction of the cross-sectional area (CSA) of the multifidus muscle on the affected segment has been found in patients with symptomatic LDH.<sup>31 32</sup> Fortin *et al*<sup>31</sup> also reported that patients with symptomatic LDH have a smaller erector spinae functional CSA (FCSA) (lean muscle mass) and FCSA/CSA ratio on the side of herniation. Position sense of the extensor musculature of the trunk has been shown to be altered in patients with LBP.<sup>33</sup> The MCE approach uses motor learning principles to facilitate coordination of the deep-trunk musculature of the spine. It seems that a MCE can alleviate pain, improve functional capacity, restore motor control, enhance the size of the CSA and strengthen trunk, abdominal and paraspinal musculature.

### Literature review

To date, several systematic reviews have looked at the effects of conservative management in patients with LDH. A systematic review and meta-analysis by Hahne *et al*<sup>6</sup> in 2010, which included 18 separate trials up to 2008, concluded that conservative management is better than no treatment in reducing pain and disability. The study consisted of English-language articles only.<sup>6</sup> In another study, Jacobs *et al*<sup>34</sup> compared the effectiveness of surgery with conservative management for LDH. Five studies were included up to October 2009. The findings of the study showed that early surgery in patients with LDH results in better short-term leg pain relief than prolonged conservative management, but no significant differences were found between surgery and usual conservative management in any of the clinical outcomes after 1- and 2-years' follow-up.<sup>34</sup> However, the studies included were of low quality and a definite conclusion could not be reached owing to their high heterogeneity.

### Why it is important to do this systematic review

Since the number of patients with LDH has increased over the past few decades,<sup>35</sup> and because systematic reviews on this topic are out of date, a new systematic review of the literature is needed. The latest available systematic review and meta-analysis comparing the effectiveness of surgery with conservative treatments for LDH was based on databases up to October 2009.<sup>34</sup> However, it did not compare conservative treatments with each other in adult patients with symptomatic LDH. As mentioned earlier, active exercise therapy can provide better outcomes than passive modalities.<sup>19</sup> MCEs are a popular approach for clinicians and researchers in the treatment of patients with LDH and many studies have been published on this topic.<sup>36–38</sup> To the best of our knowledge, this systematic review and meta-analysis will evaluate, for the first time, the effectiveness of MCEs for symptomatic LDH. Furthermore, no restriction of the language of publication will be applied in this review. The authors believe that a well-conducted systematic review and

meta-analysis is important to better inform clinicians, therapists and patients about the effectiveness of MCEs.

### Objectives

The objective of this investigation is to systematically review the literature to determine the effectiveness of MCEs in patients with symptomatic LDH.

### METHODS

The methods adopted for this review are compliant with the recommended PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analysis) checklist guidelines for systematic reviews. In addition, the PRISMA flow diagram<sup>39</sup> will be used to describe the number of primary studies that are included and excluded in each stage of the selection process (figure 1). This protocol has been prepared with regard to the PRISMA-P 2015 guidelines and has been registered in the international prospective register of systematic reviews (PROSPERO; Registration No CRD42016038166; <http://www.crd.york.ac.uk/PROSPERO>).

### Selection criteria

#### Study type

Studies will be screened for selection according to the review objectives and Participants, Interventions, Comparisons, Outcomes (PICO) criteria. We will include all clinical trials with concurrent control groups in this systematic review and meta-analysis. Studies assessing review articles, proceedings, case studies and case reports will be excluded. No restrictions to the language of publication will be applied in the selection of the primary studies. Non-English articles will be translated appropriately by free language translators on the web (Google translate, Bing, ImTranslator, Babelfish and AppliedLanguages) to assess their inclusion.

#### Population

The population will comprise non-, pre- and postsurgery groups of adult patients with symptomatic LDH. Studies will be included if they involve adult patients ( $\geq 18$  years) of both genders with referred leg symptoms, with or without LBP, where at least 75% of the participants have symptomatic LDH confirmed by MRI or CT.<sup>6</sup> Studies confirming or justifying LDH only with myelography will be excluded since disc herniations are not directly visualised by this technique.<sup>40</sup> The term 'herniation' is defined as displacement of the nucleus and/or annulus fibrosus through a tear of the annulus fibrosus.<sup>41</sup> It includes synonymous terms such as prolapse, protrusion and sequestration, but the term disc bulging is not sufficient. Studies with specific pathology, such as systemic inflammatory diseases, malformations, fractures, spondylolisthesis, scoliosis, infections, tumours and osteoporosis, will be excluded.

### Interventions

A MCE programme could be described as facilitation of the deep musculature of the spine (primarily the transversus abdominis or multifidus) at low-level sustained isometric contraction, integrated into exercise and finally, progressing into functional tasks.<sup>22 26 42</sup> A MCE programme improves the ability to ensure stability of the neutral spine position.<sup>21</sup> We will consider studies in which MCE is described as motor control, core stability or a specific stabilisation exercise and/or the study describes exercise aiming to facilitate, activate, restore, train or improve the function of the deep musculature of the spine.<sup>27 43</sup> All these different names of MCEs will be used in our search syntax. In addition, we will include trials evaluating Pilates, because the principles of Pilates may overlap with the principles of a motor control intervention.<sup>44</sup> It is important that all the studies included focus on specific muscle activity in their training programme and if a trial consists of specific stabilisation without consideration of specific muscle activity it will be excluded.<sup>43</sup> Furthermore, when MCEs are used in addition to other treatments in primary studies, they need to represent at least 50% of the total treatment programme to be included.<sup>27</sup>

### Comparators

General therapeutic exercises or any other physical therapy intervention, surgery and placebo/sham or control group.

### Outcomes

The primary outcomes of interest will be pain intensity and functional disability. The secondary outcomes are as follows: functional tests, muscle thickness, quality of life, return to work, muscle endurance and adverse events.

## SEARCH METHODS FOR IDENTIFICATION OF STUDIES

### Electronic searches

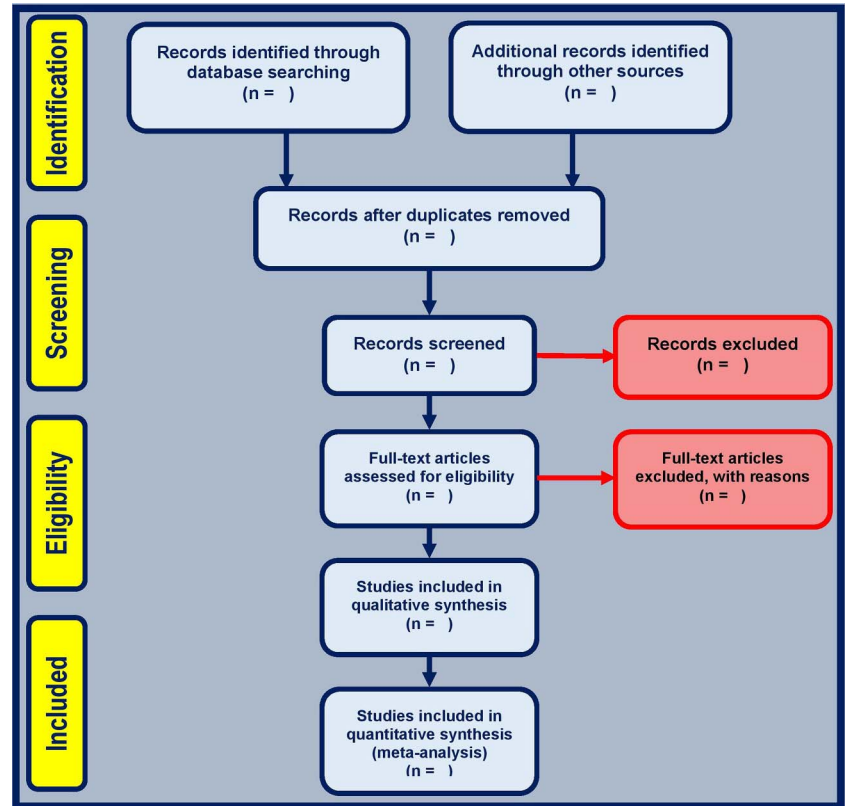
The first author (MRP) will perform electronic searches in the following databases between 1 January 1990 and 31 April 2016.

- ▶ PubMed/Medline (NLM)
- ▶ SCOPUS
- ▶ Physiotherapy Evidence Database (PEDro)
- ▶ SPORTDiscus (EBSCO)
- ▶ Cumulative Index to Nursing and Allied Health Literature (CINAHL)
- ▶ The Cochrane Central Register of Controlled Trials (CENTRAL)
- ▶ EMBASE
- ▶ ClinicalTrials.gov

### PubMed search strategy

The details of the PubMed database search syntax are presented in online supplementary appendix 1. The syntax of this systematic review is a combination of MeSH terms and free text words. The syntax will be

**Figure 1** The screening process of the study.



adopted for other databases. We will use PubMed's 'My NCBI' (National Center for Biotechnology Information) email alert service for identification of newly published systematic reviews using a basic search strategy.

If we identify additional relevant keywords during any of the electronic or other searches, we will modify the electronic search strategies to incorporate these terms and document the changes. During searching the electronic databases or reviewing reference lists in identified studies, no restrictions on the language of publication will be imposed.

### Searching other resources

Manual searches will include scanning of reference lists of included studies and similar reviews, journals that publish the most relevant research articles or reviews and other grey literature for relevant references.

Grey literature refers to reports that are difficult to locate via conventional channels and include reports, theses or dissertations, conference proceedings, newspapers, websites, fact sheets, policy documents and unpublished research and data.<sup>45 46</sup> These documents are not considered to be formally published in academic sources (ie, books or journals).<sup>45</sup> The Institute of Medicine Standards for Systematic Review and the Cochrane Handbook for Systematic Reviews of Interventions suggest incorporating grey literature in systematic reviews.<sup>46 47</sup>

If we find research that seems to match our objectives, we will contact the corresponding author(s) for missing

information and enquire about the existence of further trials. We will use recommended strategies for electronic surveys to enhance response rates.<sup>48</sup> Specifically, we will (i) send an email to the corresponding author(s), explain the review objectives and request his/her/their data; and (ii) send reminder emails at 2-, 7-, 10- and 14-week intervals after the first email. We will inform all authors that their research will be appropriately cited and they will be acknowledged in our article. If we do not receive a response from the corresponding author (s) after five emails, we will exclude the research.

### Data collection and analysis

#### Selection of studies

First, two reviewers (MRP, MT) will scrutinise titles and abstracts of all primary articles that meet the search strategy in order to determine studies eligible for inclusion. Then, the same two reviewers will independently evaluate the full text of potentially relevant non-duplicated articles. Conflicts will be resolved by discussion to reach consensus. When consensus is not reached, a third reviewer (MAS) will act as an arbitrator. Agreement between the two reviewers will be evaluated and reported using  $\kappa$  statistics and overall agreement.

#### Data extraction

Data extraction from primary articles will be performed independently by two reviewers (MRP, MT), using a quantitative data extraction form. The data extraction form for clinical trials with concurrent control groups



will be piloted previously. Any discrepancies will be resolved by consensus between the two reviewers and, when this is not possible, a third reviewer (MAS) will act as an arbitrator and make a decision on the data entered.

The following data will be extracted from all the included studies:

1. *Study characteristics*: first author's name, year of publication, country in which the study was performed, study design, size of the sample and duration of follow-up.
2. *Participants' characteristics*: age, gender, number, pre-/non- or postsurgery population and ethnicity.
3. *Intervention and comparator details*: sample size for each treatment group, blinding, type, surgery, frequency and duration of the exercise programmes, withdrawals and dropouts.
4. *Outcome measures*: pain intensity, scales and questionnaires used to assess pain, total score of functional disability, disability questionnaires, type of functional tests and their methods of assessment, instrument for measuring muscle thickness, instruments setting parameters, name of muscles and muscles' thickness (size), differences in changes of muscles thickness, indicators of return to work (eg, time to partial and to full return to work), return to work at different times, tests used to assess muscle endurance, scales and questionnaires used to measure quality of life.

#### Dealing with missing data

We will try to contact the corresponding authors of studies by email, if it is necessary to obtain data missing from published articles. However, if the authors do not respond to queries, we will calculate the missing data from other measures or estimate them from the most similar study.

#### Assessment of risk of bias of included studies

Assessment of the risk of bias (RoB) and methodological quality will be implemented by two reviewers (MRP, MT) independently considering the items according to the PEDro scale.<sup>49</sup> The PEDro scale is based on the Delphi list and has been developed by Verhagen *et al.*<sup>50</sup> Maher *et al.*<sup>49</sup> indicated that the reliability of the total PEDro score, based on consensus judgements, is acceptable. Therefore, they concluded that the scale can be used in systematic reviews of physical therapy clinical trials with control groups.<sup>49</sup> The PEDro scale items are illustrated in figure 2. Items 2–9 relate to the internal validity of an article, items 10 and 11 provide sufficient statistical information to enable appropriate interpretation of the results. Item 1 refers to the external validity (or 'generalisability' or 'applicability' of the trial) and thus is not included in the total PEDro score.<sup>51 52</sup> In addition, primary studies which attain scores of  $\geq 6$  on the PEDro scale are considered 'high quality'. Studies with a PEDro score of 4 or 5 are considered 'fair quality' and those with scores of  $\leq 3$  are considered 'poor quality'. The

PEDro scale has been used in other systematic reviews.<sup>52–54</sup>

#### Assessment of heterogeneity

All analyses will be performed using Stata V.12 software (StataCorp LP, College Station, Texas, USA) on a personal laptop. Heterogeneity among primary studies will be evaluated by the  $I^2$  statistic and  $\chi^2$  test as recommended by the Cochrane Handbook for Systematic Reviews of Interventions.<sup>46</sup> We will interpret the  $I^2$  statistic using the following guide:<sup>55</sup>

- ▶ 0–40%=no important heterogeneity;
- ▶ 30–60%=moderate heterogeneity;
- ▶ 50–90%=substantial heterogeneity;
- ▶ 75–100%=considerable heterogeneity.

We will consider heterogeneity before conducting pooled analysis. When substantial heterogeneity ( $I^2 > 50\%$ ) is evident among the studies, the results will be presented in the text qualitatively and we will not pool them. The decision to use the random-effects model will be based on our understanding of whether or not all included trials share a common effect size and not only on results of tests for statistical heterogeneity.<sup>56</sup> Therefore, when  $I^2$  values are slightly higher than 50% and there is overlap between the CIs in visual inspection of the forest plot, we will combine the results into a meta-analysis using a random-effects model.<sup>27 43</sup> A value of  $p < 0.05$  will be considered as statistically significant.

#### Assessment of publication bias

When a sufficient number of studies ( $\geq 10$ ) are identified, publication bias will be explored by a funnel plot (ie, plots of study results against precision) and Begg's and Egger's tests. We will not assess publication bias when  $< 10$  studies are available for analysis since the tests for publication bias yields unreliable results.

#### Data synthesis

##### Descriptive analysis

All included primary studies will be read in detail and presented in two separate tables. The first table will provide details of the assessment of RoB among included studies. The second table will consist of study characteristics, patient characteristics, sample size, duration of complaint, intervention and setting, and outcome data/results. Pain intensity, functional disability, functional tests, muscle thickness, return to work, muscle endurance and adverse events mean scores, together with their range (SD/95% CI) will be reported. We expect that there will be a sufficient number of clinical trial studies to carry out a meta-analysis for the primary and secondary outcomes; however, the decision to complete a meta-analysis will depend on the number of these types of study identified in the review. To perform a meta-analysis, a minimum of two studies will be required.<sup>57</sup> Stata V.12 software will be used for meta-analysis. Dichotomous data will be analysed using the risk ratio measure with its 95% CIs, whereas

## PEDro Scale

1. Eligibility criteria were specified	no <input type="checkbox"/> yes <input type="checkbox"/> where:
2. Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	no <input type="checkbox"/> yes <input type="checkbox"/> where:
3. Allocation was concealed	no <input type="checkbox"/> yes <input type="checkbox"/> where:
4. The groups were similar at baseline regarding the most important prognostic indicators	no <input type="checkbox"/> yes <input type="checkbox"/> where:
5. There was blinding of all subjects	no <input type="checkbox"/> yes <input type="checkbox"/> where:
6. There was blinding of all therapists who administered the therapy	no <input type="checkbox"/> yes <input type="checkbox"/> where:
7. There was blinding of all assessors who measured at least one key outcome	no <input type="checkbox"/> yes <input type="checkbox"/> where:
8. Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	no <input type="checkbox"/> yes <input type="checkbox"/> where:
9. All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by "intention to treat"	no <input type="checkbox"/> yes <input type="checkbox"/> where:
10. The results of between-group statistical comparisons are reported for at least one key outcome	no <input type="checkbox"/> yes <input type="checkbox"/> where:
11. The study provides both point measures and measures of variability for at least one key outcome	no <input type="checkbox"/> yes <input type="checkbox"/> where:

**Figure 2** The Physiotherapy Evidence Database (PEDro) scale; from Maher *et al.*<sup>49</sup>

continuous outcomes will be analysed using mean difference or standardised mean difference, both with their 95% CIs. Meta-analysis will be done separately on trials that evaluated the effects of MCEs in patients after surgery and on trials in which patients with symptomatic LDH had not undergone surgery. All data from the meta-analyses with 95% CI will be reported in forest plots.

### Analysis problems

If sufficient homogeneous studies are available for statistical pooling, we will conduct a meta-analysis for the time points: short (<3 months after the baseline measurements were taken), intermediate (at least 3 months but <12 months after the baseline measurements were taken) and long-term (12 months or more after the baseline measurements were taken) follow-up. If multiple time points fall within the same category, we will use the one that is closest to the end of the treatment, 6 and 12 months.<sup>27</sup>

### Subgroup analysis

Subgroup analysis will be conducted for the population. The results will be split into two separate analyses: one population with presurgery symptomatic LDH (or a population who had not undergone surgery) and the other with postsurgery symptomatic LDH. Furthermore, subgroup analysis will be performed for the secondary outcomes (functional tests, muscle thickness, quality of

life, return to work, muscle endurance and adverse events).

### Sensitivity analysis

A sensitivity analysis will be performed to test the impact of the results on the RoB assessment rated by the PEDro scale.<sup>49</sup> We will also implement sensitivity analyses to explore the effects of methodological quality and sample size on the robustness of review conclusions. Sensitivity analyses will be reported with a summary table.

### Summary of findings table

We will evaluate the quality of evidence for the main comparison at the outcome level using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.<sup>58</sup> A 'summary of findings' table will be produced in our systematic review. Five domains will be judged for each outcome in the main comparison: limitations in study design and execution (RoB), inconsistency of results, indirectness, imprecision and publication bias (reporting bias). In this systematic review and meta-analysis, limitations in the study design and execution will be assessed using the PEDro scale.<sup>49</sup> If studies have major limitations, our confidence in the estimate of the treatment effect decreases. Therefore, the quality of evidence will be downgraded.<sup>58</sup> We will consider four criteria to assess inconsistency in results: point estimates, CIs, the statistical test for heterogeneity

and the  $I^2$  test.<sup>59</sup> Indirectness will be judged by looking at the evidence tables for the target population, intervention, comparison or outcome.<sup>58</sup> In addition, results will be considered to be imprecise when studies include relatively few patients and few events but have a wide CI around the estimate of the effect.<sup>58</sup> Finally, when a sufficient number of studies ( $\geq 10$ ) are identified, publication bias will be assessed by visually examining funnel plots for evidence of asymmetry. The overall quality of the evidence supporting each outcome will be graded as high, moderate, low or very low.

- ▶ *High-quality evidence* will be identified when there are consistent findings among at least 75% of included trials.<sup>27 43 60</sup> No study design limitation is found and the data are consistent, direct and precise with no publication bias. In addition, further research is unlikely to change confidence in the estimate of effect.
- ▶ *Moderate-quality evidence* will be identified when one of the five domains is not met.<sup>27 43 60</sup> In this level, we are moderately confident about the effect estimate. However, further research is likely to affect confidence in the estimated effect and may change that estimate.
- ▶ *Low-quality evidence* will be identified when two of the five domains are not met.<sup>27 43 60</sup> In this level, our confidence in the effect estimate is limited. Further research is likely to have an important impact on confidence in the estimated effect and is likely to change that estimate.
- ▶ *Very low-quality evidence* will be identified when three of the five domains are not met.<sup>27 43 60</sup> In this level, we have little confidence in the effect estimate. Any estimate of the effect is uncertain.
- ▶ *No evidence* will be identified when none of the five domains are met.

Online supplementary appendix 2 provides more details about the five domains and the quality of evidence.

### Ethics and dissemination

Ethics approval is not required because this is a protocol for a systematic review and patients will not be involved in this research. The results of this study will be submitted to a peer-reviewed journal for publication and will also be presented at national and international academic and clinical conferences.

### DISCUSSION

LDH is the most common cause of activity limitation in people aged <45 years.<sup>61</sup> Furthermore, this condition is among the most common causes of LBP or sciatica (radicular leg pain) and imposes a heavy burden on both the individual and society.<sup>62–64</sup> Different kinds of non-invasive and invasive (surgical) treatment strategies have been suggested, with varying degrees of success.<sup>63</sup> Treatment often includes patient education, physical

therapy, alternative medicine options and pharmacotherapy. If these strategies fail, surgical intervention is usually recommended. Physical therapy is considered important for the conservative management of this problem.<sup>16</sup> Therapeutic exercises are physical therapy interventions that effectively alleviate pain and improve function for patients with LDH.<sup>10</sup> MCEs—one type of active therapeutic exercises—are a popular approach for clinicians and researchers in the conservative management of patients with LDH. To date, several systematic reviews have been published on this topic.<sup>6 34</sup> However, existing systematic reviews are out of date and none of them compared MCEs with other conservative physiotherapy interventions.

As stated earlier, non-invasive conservative treatment is the first-line choice for most patients with LDH.<sup>16</sup> Hence, a systematic review and meta-analysis is needed to evaluate the effectiveness of MCEs for symptomatic LDH. The databases which will be searched in our systematic review, the primary and secondary outcomes and the method of meta-analysis are clarified in this protocol. Our systematic review with meta-analysis will help clinicians, therapists and patients to gain a better understanding of the effectiveness of MCEs. We will try to include grey literature since some high-quality studies have not yet been published. In addition, no limitation by language will be imposed. Therefore, the limitations of this systematic review will be reduced and conclusions about the results will be improved. In this review, meta-analysis will be conducted on trials in which patients with LDH had undergone surgery and also on trials in which the patients had not undergone surgery. Our results will be important to clarify which type of exercise is most effective in LDH. Implications for future research can be drawn from the results.

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**Contributors** MRP, MT, IET, MAS, MAM-B and AAK conceived and designed the study. MRP, MT, MAS and AAK developed the search strategies and contributed to analysis of the studies. MRP and MT were responsible for the initial drafting, edited the manuscript and approved the manuscript for submission. IET, MAM-B and AAK revised the manuscript. MRP and MT will also screen potential studies, extract data and assess their quality. Any



discrepancies will be resolved by consensus between MRP and MT. When consensus is not reached, MAS will act as arbitrator.

**Competing interests** None declared.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data sharing statement** All recorded information from the data extraction process, not included in the systematic review article, will be available on request.

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