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SUMMARY WITH CRITICAL APPRAISAL

Systematic Approaches to Rehabilitative Medical Treatment of Patients: A Review of Clinical Effectiveness and Guidelines

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Authors: Casey Gray, Charlene Argaez

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Abbreviations

BREF	Abbreviated version
CI	Confidence Interval
EPA	Electrophysical agents
GRADE	Grading of Recommendations Assessment, Development and Evaluation
KOOS	Knee injury and Osteoarthritis Outcome Scale
LBP	Low back pain
MDT	Mechanical Diagnosis and Therapy
NRS	Numerical Rating Scale
PEDro	Physiotherapy Evidence Database scale
QoL	Quality of Life
RCT	Randomized Controlled Trial
RMDQ	Roland-Morris Disability Questionnaire
WHO	World Health Organization

Context and Policy Issues

The costs associated with healthcare utilization for patients requiring assessment, diagnosis, treatment, and/or aftercare in physical rehabilitation medicine in Canada are high. For example, in 2010, the number of Canadians hospitalized due to injury was reported as 231,596, and a further 3,492,148 had emergency room visits.¹ Direct healthcare costs associated with assessing, diagnosing, and treating those injuries has been estimated at \$15.9 billion.¹ It has been estimated that in Ontario, the incremental cost to manage chronic pain was \$1.742 per person, which was 51% more than a control group of patients without chronic pain.² As reported in 2011, the prevalence of chronic pain among adults in Canada was 18.9%,³ with chronic pain being more common in older adults and those who are female relative to younger adults and those who are male.³ One third of those self-reporting chronic pain rated it as very severe.³

Rehabilitation medicine is the multidisciplinary and interdisciplinary management of functioning and health.⁴ It has been stated that there is no one size fits all approach to physical rehabilitation and that systematic approaches may allow for tailoring.⁵ Systematic approaches to physical rehabilitation treatment that include assessment, diagnosis, or aftercare exist in practice. However, the comparative clinical effectiveness of these methods versus other non-systematic methods is not known.

The McKenzie Method of Mechanical Diagnosis and Therapy (MDT) is one such systematic approach.⁶ MDT is a system of assessment, classification, treatment, and prevention of recurrence for conditions of the spine and the extremities.⁶ Assessment consists of questions and a physical examination to determine how movement affects symptoms.⁶ Following assessment, the clinician classifies the patient into one of four subgroups: derangement syndrome (mechanical obstruction to movement about the joint is identified), dysfunction syndrome (mechanical loading of structurally impaired soft tissues is identified), postural syndrome (prolonged overloading of tissue is identified), or other.⁶ The treatment exercises (repeated movements and sustained postures) are distinct for each subgroup and includes patient generated forces, which are supplemented by clinician generated forces if needed.⁶ Prevention involves continued practice of the treatment movements and postures once the original symptoms have resolved.⁶

Another systematic approach is the AO Foundation's Principles of Fracture Management.⁷ Through the provision of a suite of inter-related evidence-based procedures and tools, clinicians are supported to make decisions regarding diagnosis of fractures and dislocations, indication (deciding if surgery is needed, which surgical method, and which implant or fixation device to use), preparation (correct patient positioning), approach (technique used to reach the site), reduction and fixation (surgical procedures), and aftercare (post-operative care).⁷

Although the named systematic approaches are well defined, it is not clear if there is evidence to support one systematic approach over other approaches, systematic or not (i.e., not part of a formal system).

The objective of this report is to summarize and critically appraise the evidence regarding the clinical effectiveness of systematic approaches in rehabilitative medical treatment of patients. A second purpose is to summarize and appraise the evidence-based guidelines on the same subject.

Research Questions

1. What is the clinical effectiveness of systematic approaches to physical rehabilitation treatment?
2. What are the evidence-based guidelines regarding systematic approaches to patients receiving physical rehabilitation treatment?

Key Findings

Evidence of moderate to high quality from a systematic review of RCTs suggested that systematic approaches to rehabilitation medicine, specifically the McKenzie Method of Mechanical diagnosis and treatment (MDT), may be effective for reducing pain and disability for patients with acute or chronic low back pain. Comparative effectiveness in the included studies varied by comparator examined. In the systematic review and four RCTs there were no differences between MDT and comparators for any psychological constructs assessed (i.e., global perceived effect of treatment, kinesiophobia, and quality of life).

Evidence of limited quality from one non-randomized study of patients with knee osteoarthritis who were waitlisted for surgery suggested that MDT may be an effective treatment approach. Patients diagnosed with derangement syndrome who were treated with MDT exercises experienced greater improvements in pain intensity, pain in daily living, and function in daily living than (i) patients diagnosed as not having derangement syndrome who were treated with standard exercises and (ii) undiagnosed patients in a waitlist condition.⁸

No evidence-based guidelines were identified regarding systematic approaches to physical rehabilitation treatment.

Methods

Literature Search Methods

A limited literature search was conducted on key resources including PubMed, Medline, and The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD)

databases and a focused Internet search. Methodological filters were applied to limit retrieval to systematic reviews, health technology assessments, and meta-analyses, randomized controlled trials, non-randomized studies, and guidelines. The search was limited to English language documents published between January 1, 2013 and October 11, 2018.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Patients of any age receiving physical rehabilitation treatment
Intervention	Systematic approaches (combinations of assessments, treatments, and/or after care therapies from presentation to resolution of the problem or disease state)
Comparator	No comparator; non-systematic approaches; systematic approaches; any comparator
Outcomes	Clinical effectiveness; guidelines
Study Designs	Health technology assessments, systematic reviews, meta-analyses, non-randomized studies, evidence-based guidelines

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published prior to 2013. Guidelines with unclear methodology were also excluded.

Critical Appraisal of Individual Studies

The included systematic reviews were critically appraised by one reviewer using AMSTAR 2⁹ and randomized studies were critically appraised using the Cochrane Collaboration's tool for assessing risk of bias in randomized studies.¹⁰ The non-randomized study was also appraised using the Cochrane risk of bias tool.¹⁰ The subgroup analyses eligible for this report broke randomization, however the study was designed and registered as a Randomized Control Trial and this tool was deemed appropriate. Summary scores were not calculated for the included studies; rather, a review of the strengths and limitations of each included study were described narratively.

Summary of Evidence

Quantity of Research Available

A total of 520 citations were identified in the literature search. Following screening of titles and abstracts, 498 citations were excluded and 22 potentially relevant reports from the electronic search were retrieved for full-text review. One potentially relevant publication was retrieved from the grey literature search for full text review. Of these potentially relevant articles, 16 publications were excluded for various reasons, and 6 publications met the inclusion criteria and were included in this report. These comprised one systematic review

with meta-analysis, four RCTs, and one non-randomized study. The four RCTs were included in the systematic review, however some relevant outcomes were reported in the RCT publications and not the systematic review, thus the RCTs were included in this review. Outcomes that were reported in both the SR and RCTs are reported in this report within the results of the SR. No relevant evidence-based guidelines were identified. Appendix 1 presents the PRISMA¹¹ flowchart of the study selection.

Summary of Study Characteristics

Additional details regarding the characteristics of included publications are provided in Appendix 2.

Study Design

The included systematic review (with meta-analysis) of 12 RCTs was published in 2018 and was not registered a priori.¹² The last search was conducted September 6 2017 and was not limited by date. Inclusion criteria were RCT design and training in MDT by the therapists.¹²

Four RCTs¹³⁻¹⁶ and one non-randomized study⁸ were included. Patients in the non-randomized study were initially randomized to exercise or comparator group. The exercise condition was further divided based on MDT diagnosis of derangement syndrome (assigned to McKenzie Method) or other (assigned to exercise comparator), resulting in three groups.⁸

Country of Origin

The systematic review and non-randomized study were conducted in Canada.^{8,12} The RCTs were published by authors from Brazil,^{13,16} Australia,¹⁴ and Kosovo.¹⁵

Patient Population

Data from 2,225 patients is included in this report. Data included in the systematic review were from 2,045 adults with acute or chronic low back pain.¹² The mean age reported in included studies ranged from 35 to 54 years.¹² Patients in the RCTs were 638 outpatients seeking care for nonspecific low back pain (patients already counted in the systematic review).¹³⁻¹⁶ Across intervention and comparator groups, patient mean age ranged from 47.5 to 57.47 years.¹³⁻¹⁶ Patients in the non-randomized study were 180 waitlisted orthopedic surgery patients with radiologically confirmed osteoarthritis of the knee, with a mean age of 64 years.⁸

Interventions and Comparators

All included studies examined the McKenzie Method of MDT as the intervention of interest for the purposes of this report. The McKenzie Method involves a systematic approach to treatment that involves assessment, diagnosis and treatment by physiotherapists with training in the McKenzie Method. In all but one clinical study¹⁵ the therapist delivering the intervention was a certified McKenzie Method practitioner.

Comparators were manual therapy and exercise,¹² exercise,^{12,14} education,¹² placebo,^{12,13} “other interventions,”¹² electrophysical agents,¹⁵ and waitlist.⁸ Other interventions were defined as nonsurgical and noninvasive interventions within the scope of physical therapy practice (eg, exercise, manual therapy, and education).¹²

Intervention treatments ranged in duration from five to nine weeks whereas comparator treatments ranged from four to eight weeks in duration.^{8,12-16} Across all groups (intervention

and comparators) number of sessions ranged from no minimum number of treatments up to 12 sessions, sessions lasted 30 to 40 minutes each, and occurred once to twice per week.^{8,12-16}

Outcomes

Pain

Studies in the systematic review defined pain was defined as average pain intensity for the past 7 days; pain in daily living; bothersomeness of back/leg pain; numbness/tingling; and back pain and leg pain.^{12,13} Pain was measured with the 11-item Pain Numerical Rating Scale original and Brazilian-Portuguese versions; scores range from 0 (no pain) to 10 (worst pain imaginable).¹² Garcia et al. indicated the scale had acceptable psychometric properties and suggested a 20% decrease in pain would be considered clinically important.¹³ Low back pain was also assessed using the visual analog scale; Low Back Pain Rating Scale; Faces Pain Scale-Revised; Short form McGill Pain Questionnaire.¹² In the non-randomized study, pain intensity (in the morning, afternoon, evening and in the previous two days) was assessed using the 4-item P4 pain scale.⁸ Knee pain in daily living was assessed using the 41-item Knee injury and Osteoarthritis Outcome Score (KOOS) questionnaire.⁸ Responses to items on the KOOS are rated on a 5-point scale, subtotals are calculated for five subscales and converted to a 0-to-100 scale, with higher scores indicating less pain.⁸ Rosedale et al. reported that the KOOS has good psychometric properties.⁸

Disability and Function

The systematic review by Lam et al. sought out to assess disability as an outcome. Where studies reported function and not disability (i.e., Haliday et al. 2016),¹⁴ function was included in the meta-analysis. Where studies reported function and disability, (i.e., Garcia et al. 2018) only disability was included in the meta-analysis.¹²

Disability was described in Garcia (2013) as difficulty performing tasks.¹⁶ Disability was assessed in included studies using the Oswestry Disability Questionnaire; the original, modified, and Brazilian-Portuguese versions of the Roland-Morris Disability Questionnaire (RMDQ);^{12,16} and disability items from the Low Back Pain Rating Scale. As described by Garcia et al. (2018) indicated the RMDQ had acceptable psychometric properties and suggested a 20% decrease in disability would be considered clinically important.^{13,8} No details were provided regarding the Oswestry Disability Questionnaire or the Low Back Pain Rating Scale.¹²

Function was not defined in any study and was assessed using the original and Brazilian-Portuguese versions of the Patient-Specific Functional Scale, the physical functioning subscale from the 36-Item Short Form Health Survey (SF-36), the Functional Status Questionnaire, and the Function in Daily Living subscale of the KOOS.⁸ With the Patient-Specific Functional Scale, patients identified difficult to perform tasks at baseline. At subsequent assessments, activities rated by patients as being difficult to perform at baseline were rated again to indicate current difficulty with the task on a scale from 0 (unable to perform activity) to 10 (able to perform activity at the same level as before injury or problem). The potential range of scores varies across patients and depends on the number of difficult tasks identified at baseline. Function in daily living was assessed using the subscale of the KOOS questionnaire.⁸ Scores were converted to a 0 to 100 scale, with higher scores indicating greater function.⁸ Rosedale et al. reported that the KOOS has good

psychometric properties.⁸ No details were provided regarding the SF-36 or Functional Status Questionnaire,¹² Authors did not specify what would represent a clinically meaningful change.¹² No details were provided regarding the Functional Status Questionnaire.¹²

Mobility

Mobility of the spine and hips was assessed in one study¹⁵ using the Fingertip-to-Floor Distance test. Standing on a platform, patients are instructed to bend at the hips and reach toward their toes or beyond. Distance was positive when subjects did not reach the platform and negative when reached further than the platform. Murtezani et al. did not specify what would represent a clinical meaningful change and validity of the measure was not reported.¹⁵ Trunk flexion range of motion was measured in one study in degrees using an inclinometer.¹⁶ With the inclinometer attached to the patient on the right hand side of the trunk, patients crossed their arms and were instructed to bend over as much as possible. Garcia reported data from a validation study suggesting good interrater reliability and validity of the inclinometer.¹⁶

Perceived Effect of Treatment

Perceived effect of treatment was assessed in two studies^{13,14} using the 11-item Global Perceived Effect Scale. Items were rated on a scale ranging from -5 (vastly worse) to +5 (completely recovered). The potential range of scores was not reported. Authors did not specify what would represent a clinically meaningful change for secondary outcomes.¹³

Kinesiophobia

Kinesiophobia was assessed in one study¹³ using the 17-item Tampa Scale of Kinesiophobia, Brazilian-Portuguese version. Scores ranged from 7 (no kinesiophobia) to 68 (high kinesiophobia). Garcia et al. 2018 did not specify what would represent a clinically meaningful change for secondary outcomes.¹³

Quality of Life

Quality of Life was assessed in one study using the 16-item World Health Organization Quality of Life-BREF instrument (WHOQoL-BREF).¹⁶ The WHOQoL-BREF assesses quality of life in 4 domains, with high scores representing good quality of life. A psychometric study cited by Garcia et al indicates the scale as acceptable validity and reliability.¹⁶

Adverse Effects

Adverse effects were assessed in two studies. Patient complaints were recorded at each treatment point in one study.^{13,16} The method for assessing adverse events was not described in the second study.¹³

Summary of Critical Appraisal

The critical appraisal of the systematic review, RCTs and the non-randomized study are summarized here. Additional details regarding the strengths and limitations of included publications are provided in Appendix 3.

Systematic Review

One systematic review was assessed using AMSTAR 2.⁹ Strengths of the systematic review included having a clear research question and inclusion criteria, extensive and up-to-date database searching, use of an established tool for assessing risk of bias in included

studies (i.e., the PEDro scale), and a transparent discussion of potential sources of bias in the findings.¹²

There were several limitations in the reporting of the included systematic review.¹² For instance, in the description of study methods, authors described using GRADE to assess the quality of the body of evidence across outcomes, yet this assessment was not reported.¹² It is unclear if review methods were established a priori, if registries or grey literature were searched, or if data extractors achieved consensus on the data to extract from included studies, as these were not reported.¹² Authors identified significant statistical heterogeneity in three meta-analyses but did not report adjusting for heterogeneity or investigating the cause.¹² Related to heterogeneity, the treatment of data for the disability outcome was problematic. Where studies reported disability and function, disability data were combined in the meta-analysis.¹² Where studies only reported function, function data were entered into the meta-analysis.¹² This presents two issues.¹² First, the review authors never defined disability or described the decision to consider function and disability as synonymous.¹² Second, it is not clear if function was systematically searched, and it is clear that all available function data were not captured in the review, calling the internal validity of the study into question.¹²

RCTs

The four RCTs¹³⁻¹⁶ were assessed using the Cochrane Collaboration's tool for assessing risk of bias in randomized trials.¹⁰ The four RCTs¹³⁻¹⁶ eligible for inclusion in this report were also included in the systematic review.¹² The critical appraisal described here only applies to those outcomes incompletely or not reported in the systematic review.

Strengths of the RCTs included a low risk of selection bias, as all RCTs used a computer-generated random sequence to allocate participants to groups. The random sequence was prepared by an investigator uninvolved in treatment^{13,14,16} or assessment of patients.^{13,16} Murtezani et al. did not describe the person who prepared the sequence.¹⁵ Additional strengths include the low risk of selection bias due to allocation concealment, given that all studies used an allocation concealment strategy involving opaque envelopes.¹³⁻¹⁶ The risk of detection bias was judged to be low as outcome assessors were reportedly blinded in all studies and there is no reason to expect blinding was not effective.^{1,7,10,13}

A limitation of one of the included studies includes risk of selective reporting bias. In one study, by Garcia et al., outcomes were described in an a priori published study protocol, with planned reporting for 1, 3, and 6 month follow up for all outcomes, including trunk flexion range of motion. However, in the published results paper trunk flexion range of motion was only reported at 1 month follow up, with authors explaining this was planned a priori to avoid potential loss to follow-up at 3 and 6 months after randomization.¹⁶ (p.733)

Non-Randomized Study

The non-randomized study⁸ was assessed using the Cochrane risk of bias tool.¹⁰ Strengths of the included quasi-RCT included assignment to exercise and control conditions using a random number generator operated by an independent person, use of an allocation concealment strategy involving opaque envelopes, and blinding of outcome assessors.⁸

Limitations included the breakdown of the randomization strategy upon further assigning participants in the exercise condition to MDT or other evidence-based exercise condition based on response to MDT assessment.⁸ Furthermore, the inclusion of participants with

osteoarthritis who were waitlisted for knee surgery potentially limits the generalizability of the findings to patients with less severe conditions.⁸

Summary of Findings

Clinical Effectiveness of Systematic Approaches to Physical Rehabilitation Treatment

Pain

Pain was reported in all of the included studies. However, only those results not reported in the systematic review of RCTs are reported here to avoid double counting.

Based on systematic review evidence the McKenzie Method of MDT was statistically significantly more effective at improving acute low back pain compared with manual therapy combined with exercise, but did not differ from “other interventions, which were a composite of all active treatment comparators”¹²

For chronic low back pain, MDT was significantly more effective than “other interventions”¹² but did not differ from manual therapy combined with exercise or exercise alone.¹² There was significant statistical heterogeneity identified in the meta-analyses for chronic low back pain and these findings should be interpreted cautiously.¹² In one RCT, compared with placebo, MDT was more effective at improving low back pain at 5 week follow up but not at 3, 6 or 12 months in patients classified as derangement syndrome.¹³

For chronic knee pain intensity, the included NRS found that MDT was more effective than evidence-based exercises at two-week follow-up, but effectiveness was not clear at three months, as P-values were reported as less-than or equal-to 0.05 for this time point.⁸ There was also a lack of clarity around statistical significance for MDT compared with waitlist (significance was reported as less-than or equal-to 0.05), however based on confidence intervals it appears that MDT was more effective than waitlist at two-week but not three-month follow up.⁸ Regarding knee pain experienced in daily living, MDT appears to have been more effective than evidence-based exercises and no treatment (waitlist) at two-week follow up but not at three months.⁸

Disability

Disability was reported in all of the included studies. However, only those results not reported in the systematic review of RCTs are reported here.

Based on the evidence reported in the included SR, for acute low back pain-related disability, MDT was not significantly different than manual therapy combined with exercise or “other interventions.”¹² For chronic low back pain-related disability, MDT was more effective than “other interventions” and exercise alone, but not manual therapy combined with exercise.¹² In one RCT, MDT did not differ from placebo at five weeks or three-, six-, or 12-month follow-up in patients classified as derangement syndrome.¹³

Function

MDT did not differ from placebo or motor control exercises for functional improvements in patients with low back pain classified as derangement syndrome in two RCTs.^{13,14} In patients with knee osteoarthritis, MDT showed greater improvements in function in daily living than evidence-based exercises and a waitlist comparator condition at two-week follow up, but not at three-month follow up in one non-randomized study.⁸

Mobility

Flexibility at the hips in patient with low back pain showed greater improvements with MDT compared with EPAs at four weeks and two- and three-month follow up in one RCT.¹⁵ Range of motion did not differ between MDT and Back School in patients with low back pain at one-month follow-up in another RCT.¹⁶

Perceived Effect of Treatment

MDT did not differ from placebo for global perceived effect of treatment in patients with low back pain classified as derangement syndrome in two RCTs.^{13,14}

Kinesiophobia

MDT did not differ from placebo for kinesiophobia in patients with low back pain classified as derangement syndrome.¹³

Quality of Life

There was no significant difference between MDT and Back School for quality of life at one-, three-, or six-month follow-up in one RCT.¹⁶

Adverse Effects

No adverse effects were reported for MDT in two RCTs examining low back pain.^{13,16} One participant in the Back School comparison group reported temporary exacerbation of pain during the third treatment session.¹⁶

Guidelines

No evidence-based guidelines regarding systematic approaches to patients receiving physical rehabilitation treatment were identified for inclusion in this report. Therefore, no summary can be provided.

Appendix 4 presents a table of the main study findings and authors' conclusions.

Limitations

The included studies were of moderate-to-high methodological quality (Appendix 3), however there were limitations related to gaps in the literature. While studies were identified regarding the use of the McKenzie Method of MDT, eligible studies regarding other systematic approaches were not identified. Furthermore, most of the identified literature examined adult patients with low back pain, and one study examined patients with knee osteoarthritis, potentially limiting the generalizability of the current findings to other patient populations and age groups. All included studies imposed an upper limit on the number of treatment sessions patients could engage in. This is inconsistent with the McKenzie Method of MDT, in which treatment providers make decisions about the number of treatments based on individual patients and their progress and needs, and potentially limits the ecological validity of the findings. All included studies examined adults between the ages of 35 and 54 years of age. It is not known how patients in pediatric or geriatric age groups would respond to MDT. Finally, no guidelines were identified regarding the use of systematic approaches in rehabilitative medicine.

Conclusions and Implications for Decision or Policy Making

One systematic review, four RCTs, and one non-randomized study regarding the clinical effectiveness of systematic approaches to physical rehabilitation treatment were included in this review.

Overall, evidence was mixed. In general, the McKenzie Method of MDT was associated with improved pain, disability, function, and range of motion, but the comparative effectiveness varied depending on the comparator, and whether the outcome was acute or chronic.

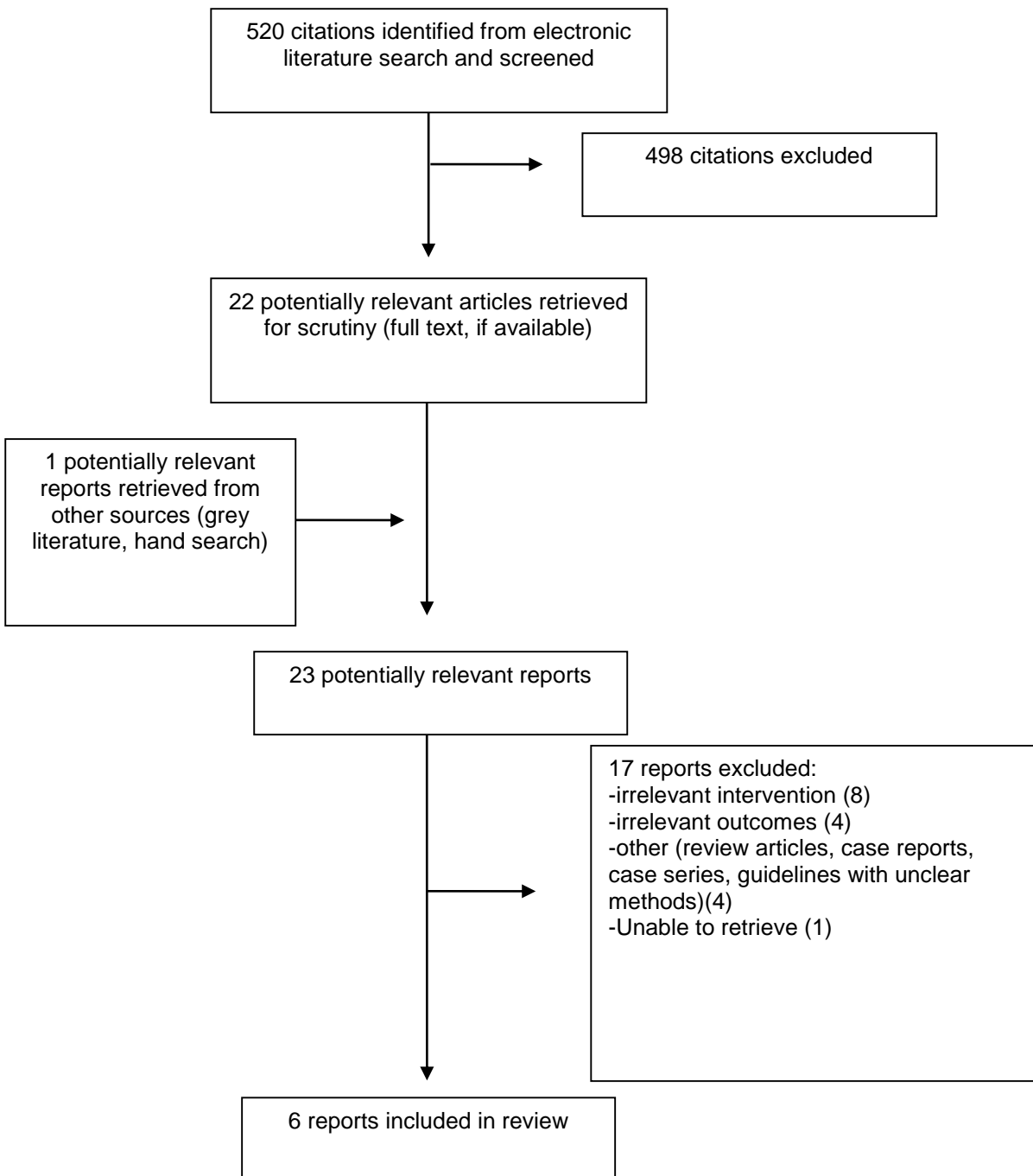
The included studies were of moderate-to-high quality, but were subject to some limitations. All studies imposed a maximum number of treatment sessions on the intervention condition. This is contrary to the McKenzie Method protocol, which instructs therapists to tailor the number of sessions to the progress and needs of the individual patient, limiting the ecological validity of the included trials. All studies examined low back pain or osteoarthritis-specific knee pain limiting the generalizability to other patient populations.

Since all included studies examined the McKenzie Method of MDT, no conclusions can be made regarding the effectiveness of other systematic approaches to physical rehabilitation treatment or systematic approaches overall. No evidence-based guidelines were identified to inform best-practices. Uncertainty would be reduced with large, high quality randomized trials examining various patient groups and other systematic approaches to physical rehabilitation medicine.

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Appendix 1: Selection of Included Studies



Appendix 2: Characteristics of Included Publications

Table 2: Characteristics of Included Systematic Review and Meta-Analysis

First Author, Publication Year, Country	Study Designs and Numbers of Primary Studies Included	Population Characteristics	Intervention and Comparator(s)	Clinical Outcomes, Length of Follow-Up
Lam, 2018 ¹² Canada	12 RCTs	2045 patients (intervention n = 1,066; comparator n = 979) with acute (<12 weeks duration) or chronic (>12 weeks duration) LBP Mean age range: 35 to 54	Intervention: McKenzie Method of MDT Comparators: (i) Other interventions (composite score of ii to iv) (ii) Manual therapy and exercise (iii) Exercise (iv) Education (v) Placebo	(i) Pain (ii) Disability Follow up range: 1 week to 12 months

LBP = low back pain; MDT = Mechanical Diagnosis and Therapy; RCT = randomized controlled trial

Table 3: Characteristics of Included Primary Clinical Studies

First Author, Publication Year, Country	Study Design	Population Characteristics	Intervention and Comparator(s)	Clinical Outcomes, Length of Follow-Up
RCTs				
Garcia, 2018 ¹³ Brazil	Assessor blinded 2-arm randomized placebo controlled RCT of physical therapy outpatients recruited between May 2014 and July 2015 All patients were assessed for directional preference pre-randomization -Prospectively registered	Patients (N = 148) seeking care for chronic non-specific low back pain McKenzie Method group: n = 74 (58 female, 16 male) Mean age = 57.47 Placebo group: n = 74 (1 excluded after randomization due to cancer diagnosis [ineligible], results analyzed out of 73) (54 female, 19 male) Mean age = 55.47	Intervention: McKenzie Method of MDT Duration = 5 weeks 10 treatment sessions, 2 x per week, 30-40 minutes per session Comparator: Placebo Detuned pulsed ultrasound and detuned short wave diathermy in pulsed mode with disconnected internal cables. 30 minutes per session Duration = 5 weeks 10 treatment sessions, 2 x per week, 30-40 minutes per session	Pain Intensity Average pain intensity over the last 7 days measured using the 11-point NPRS Brazilian-Portuguese version; scores range from 0 (no pain) to 10 (worst pain imaginable); measurement properties not clearly reported. A 20% decrease was considered clinically important Function Patient-Specific Functional Scale Brazilian-Portuguese version; 17 items. Compares function

First Author, Publication Year, Country	Study Design	Population Characteristics	Intervention and Comparator(s)	Clinical Outcomes, Length of Follow-Up
				<p>against baseline levels. Therefore, potential range of scores varies across patients.</p> <p>Perceived effect of treatment: Global Perceived Effect Scale; 11-point – 5 (vastly worse) to +5 (completely recovered) scale [range of scores not reported]</p> <p>Kinesiophobia Tampa Scale of Kinesiophobia Brazilian-Portuguese version; scores ranged from 17 (no kinesiophobia) to 68 (high kinesiophobia)</p> <p>Follow up at 5 weeks, and 3, 6, and 12 months post-randomization for pain and disability</p>
<p>Halliday, 2016¹⁴</p> <p>Australia</p>	<p>Single centre, assessor blinded 2-arm RCT of consecutive patients referred for low back pain between April 2011 and March 2013</p> <p>-blinded assessor</p>	<p>Patients (N = 70) with chronic low back pain with a directional preference seeking physical therapy were enrolled</p> <p>McKenzie Method group n = 35; mean age = 48.8 (28 female, 7 male)</p> <p>Motor control exercises n = 35; mean age = 48.3 (28 female, 7 male)</p>	<p>Intervention: McKenzie Method Progression according to therapist judgement of patient need, adhering to principles of MDT</p> <p>Duration = 8 weeks No minimum, up to 12 treatments</p> <p>Comparator: Motor control exercises; Patients progressed after meeting specific criteria for each phase</p> <p>Duration = 8 weeks No minimum, up to 12 treatments</p>	<p>Perceived Effect of Treatment: Global Perceived Effect questionnaire; scores range from – 5 (vastly worse) to +5 (completely recovered) scale; Additional description not provided]</p> <p>Pain intensity included in Lam, 2018¹²</p> <p>Follow up at 8 weeks</p>

First Author, Publication Year, Country	Study Design	Population Characteristics	Intervention and Comparator(s)	Clinical Outcomes, Length of Follow-Up
Murtezani, 2015 ¹⁵ Kosovo	Single-centre RCT Conducted between June 2009 and January 2012	Workers in an occupational health centre who complained of work related nonspecific chronic low back pain (N = 272) McKenzie Method group (n = 34); mean age 48.8 ; 83 (74.8%) men; 28 (25.2%) women EPAs group (n = 138); mean age 47.5; gender = 42 (38.5%) men, 67 (61.5%) women	Intervention: McKenzie Method [delivered by therapists who were not certified specialists in the McKenzie method, but had 50 hours of training] assessed and diagnosed as derangement, dysfunction and postural syndrome; repeated after 48 hours to confirm; [those who did not experience the centralization of pain were dropped from the study and alternative treatment was arranged] Individually planned Exercises repeated 5 x per day, 10-15 repetitions, depending on stage of disease and pain. First assessment and treatment lasted 1 hour. Subsequent treatments lasted 30-45 minutes. Max 7 treatments over 9 weeks Comparator: Electrophysical agents (interferential current, ultrasound, heat) in prone position Duration = 4 weeks, 10 sessions	Mobility of spine and hips: Fingertip-to-floor distance test; distance between tip of middle finger and the floor measured with a tape measure (cm). Distance was positive when subjects did not reach the platform and negative when reached further than the platform Other outcomes included in Lam, 2018 ¹² Follow up at 3 months
Garcia, 2013 ¹⁶ Brazil	Single centre, assessor blinded, 2-arm RCT of physical therapy outpatients recruited between July 2010 and July 2012 All patients were assessed for	Patients (N = 148) seeking care for chronic (≥ 3 months) nonspecific low back pain McKenzie Method group: n = 74 (58 female, 16	Intervention: McKenzie Method Duration = 4 weeks, 1 in person session per week plus home sessions Each week included an	Trunk flexion range of motion: Inclinometer; protocol not described QoL: WHOQoL-BREF; scores range from 0 to 100)

First Author, Publication Year, Country	Study Design	Population Characteristics	Intervention and Comparator(s)	Clinical Outcomes, Length of Follow-Up
	directional preference pre-randomization -Prospectively registered	male) Mean age = 53.70 (1.53) Back School group: n = 74 (51 female, 23 male) Mean age = 54.16 (1.57)	education and a McKenzie exercise component. McKenzie exercises progressed each week as individually tailored. Comparator: Back School Duration = 4 weeks Week 1 – individual session Week 2 to 4 – group sessions offered advice and exercises. Progression followed the program sequence (not individually tailored)	Follow up at 1, 3, and 6 for all outcomes except adverse effects (recorded during each treatment session) and trunk flexion range of motion (reported inconsistently as 1 month post randomization only, or 1 month post-randomization and immediately following treatment) Pyschometric properties were not reported for any instrument. Other outcomes included in Lam, 2018 ¹²
Non-Randomized Trials				
Rosedale, 2014 ⁸ Canada	Single centre, blind assessor, 2-arm quasi-RCT of physiotherapy outpatients recruited between November 2009 and April 2012 Patients were randomized to exercise or waitlist. Exercise was further grouped following MDT assessment for derangement (assigned to MDT) or non-derangement (assigned to other exercises)	Wait listed orthopedic surgery patients (N = 180) with knee pain for >4 months with radiologically confirmed diagnosis of knee osteoarthritis Following MDT assessment for derangement: McKenzie Method group n = 40 patients with derangement syndrome; age = 68 years; 22 (55%) female, 18 (45%) male Standard exercises group n = 59 patients without derangement syndrome; age = 64 years; 33 (56%) female, 26 (44%)	Intervention: McKenzie Method 4 to 6 physiotherapy sessions over 2 weeks; included 2 to 3 assessment sessions (1 hour initial assessment, 20 minute subsequent sessions) Comparators: (i) Home-based exercises prescribed at 10 repetitions every 2-3 hours (ii) Waitlist (usual care)	Pain intensity The 4-item P4 Pain Scale; scores range from 0 (no pain) to 40 (highest possible pain) Pain and function in daily living subscales The KOOS survey Follow up at 2 weeks and 3 months

First Author, Publication Year, Country	Study Design	Population Characteristics	Intervention and Comparator(s)	Clinical Outcomes, Length of Follow-Up
		males Waitlist group n = 60 patients not assessed for derangement syndrome; age = 64 years; 34 (60%) female, 25 (40%) male		

BREF = abbreviated version; EPA = Electrophysical agents; MDT = Mechanical Diagnosis and Therapy; NPRS = numerical pain rating scale; QoL = Quality of Life; RCT = randomized controlled trial; RMDQ = Roland-Morris Disability Questionnaire; WHO = World Health Organization

Appendix 3: Critical Appraisal of Included Publications

Table 4: Strengths and Limitations of Systematic Reviews and Meta-Analyses using AMSTAR 2⁹

Strengths	Limitations
Lam, 2018 ¹²	
<p>Research questions and inclusion criteria for the review included the components of PICO</p> <p>The review authors searched six electronic databases, provided key word and MEDLINE search strategy, searched the references lists of included studies, and conducted the search within 24 months of completion of the review. There was no specific mention of inclusion or consultation with content experts in the field, however author list credentials include physical rehabilitation academics and practitioners.</p> <p>Two reviewers independently agreed on selection of eligible studies. If consensus could not be achieved a third reviewer made the decision</p> <p>Data extraction was performed by 2 independent investigators who each independently extracted the data from all studies.</p> <p>The quality of included studies was assessed using the PEDro scale.</p> <p>Appropriate statistical techniques were used to combine the data (i.e., random effects meta-analysis)</p> <p>Review authors discussed the potential impact of risk of bias on the results of the meta-analyses</p> <p>The study was funded by the International MDT Research Foundation. Authors reported that funding did not influence any component of the study, and not conditions or restrictions were placed on the use or publication of data</p>	<p>Review methods were not established prior to the conduct of the review</p> <p>Not reported if trial registries, study registries, or grey literature were searched</p> <p>No explanation for including only RCTs or restricting to English and French language studies</p> <p>Unclear if data extractors achieved consensus on which data to extract from included studies. Where studies reported both disability and function, disability data were abstracted. Where studies only reported function, function data were abstracted. Disability and function were not defined.</p> <p>Included studies were described in partial detail; comparators were not adequately described</p> <p>Sources of funding for included studies was not reported</p> <p>Significant heterogeneity was identified in three meta-analyses; authors did not report adjusting for heterogeneity or investigating the cause</p> <p>Authors reported that the quality of the body of evidence for each outcome was assessed using GRADE. GRADE tables or other uses of GRADE were not reported in the results.</p> <p>One study was excluded due to serious methodological concerns whereas other low quality studies were retained for inclusion.</p> <p>Authors did not report investigating publication bias (small study bias)</p>

GRADE = Grading of Recommendations Assessment, Development and Evaluation, MDT = Mechanical Diagnosis and Treatment; PEDro = Physiotherapy Evidence Database; PICO = participants, interventions, comparators, outcomes;

Table 5: Strengths and Limitations of Clinical Studies using the revised Cochrane Risk of Bias Tool for randomized trials¹⁰

Strengths	Limitations
RCTs	
Garcia, 2018 ¹³	
<p><u>Selection bias</u> Random sequence generation A computer generated randomization sequence was generated by an investigator uninvolved in treatment or assessment of patients; comparable groups were produced, i.e., similar number of co-interventions in both groups</p> <p>Allocation concealment Intervention allocations likely could not have been foreseen in before or during enrollment. An investigator uninvolved in treatment or assessment used consecutively numbered, sealed, opaque envelopes to conceal group allocation. Prior to each treatment session, envelopes were sequentially opened by the therapist following the baseline assessment of each participant according the McKenzie Method approach.</p> <p><u>Performance bias</u> Blinding of participants Blinding of patients was likely effective.</p> <p><u>Detection bias</u> Blinding Blinding of outcome assessors was likely effective</p> <p><u>Attrition bias</u> Incomplete outcome data Between 97.3% and 99.3% of patients completed follow-up assessment in each treatment group at each follow-up point. Adherence to treatment was high (patients attended 9.01 and 9.23 sessions out of a possible 10 in the intervention and comparator groups, respectively. Intention to treat analysis was used.</p> <p><u>Reporting bias</u> Selective reporting Selective reporting not detected. The study protocol was registered a priori and reportedly followed without changes.</p>	<p><u>Performance bias</u> Blinding of personnel It was not possible to blind personnel (physiotherapist) to group allocation due to the nature of exercise interventions. However, different therapists treated intervention and comparator groups to minimize potential for differential treatment.</p> <p><u>Other potential sources of bias</u> As the groups were different in the amount of exercise, the placebo used does not enable us to determine if any differences were a result of exercise generally or specifically due to mechanisms associated with the MDT approach.</p> <p>Authors pre-specified the duration of MDT, which is inconsistent with MDT in practice.</p>
Halliday 2016 ¹⁴	
<p><u>Selection bias</u> Random sequence generation A randomization sequence was created using computer-generated numbers by a researcher not involved with data collection.</p> <p>Allocation concealment Intervention allocations likely could not have been foreseen before or during enrollment. Following baseline data collection, a research assistant who was unaware of the randomization</p>	

Strengths	Limitations
<p>sequence opened the sequentially numbered, opaque, sealed envelopes to assign patients to groups.</p> <p>Performance bias Blinding of participants and personnel There was no mention of blinding of participants or personnel. Due to the nature of exercise interventions, it would not be possible to blind personnel</p> <p>Detection bias Blinding of outcome assessment Blinding of outcome assessors was likely effective.</p> <p>Attrition bias Incomplete outcome data Loss to follow-up was low; 8 participants (11.4%) were not available for data collection for primary outcomes at 8 week follow up (3 McKenzie Method group; 5 motor control group) due to time constraints (n = 5), dissatisfaction with treatment (n = 2), inability to attend treatment sessions (n = 1). Authors indicated intention to treat was used, regardless of compliance with protocol.</p> <p>Reporting bias Selective reporting Selective reporting not detected</p> <p>Other sources of bias avoided Treatment frequency for each participant was determined by the clinical judgement of the treating physical therapist, up to a 12-session maximum in the 8 week study duration. Interventions were delivered according to participant needs based on the allocated treatment, which is somewhat consistent with how MDT would be performed in practice.</p>	
Murtezani, 2015 ¹⁵	
<p>Selection bias Random sequence generation Randomized with a computer-generated random number sequence on a 1:1 basis.</p> <p>Allocation concealment Intervention allocations likely could not have been foreseen before or during enrollment. Groups were coded and the allocation transferred to sealed, sequentially numbered envelopes.</p> <p>Detection bias Blinding Blinding of outcome assessor was likely effective</p> <p>Reporting bias Selective reporting Selective reporting not detected</p>	<p>Selection bias Random sequence generation It is unclear how the person who facilitated blind randomization was associated with the trial.</p> <p>Random sequence generation / allocation concealment It is unlikely randomization was achieved. Participants randomized to the intervention group underwent physical assessment. Those who did not experience the centralization of pain were dropped from the study (n not reported). Research reported in this study indicates that a favorable treatment response is expected when centralization is obtained. Participants in the comparator group were not assessed for centralization of pain and therefore it is not known what effect this change had on the results. Eliminating the non-responders from the intervention group analyses is problematic.</p>

Strengths	Limitations
	<p><u>Performance bias</u> Blinding of participants and personnel Allocated interventions were known to participants and personnel during the study</p> <p><u>Attrition bias</u> Incomplete outcome data Authors reported low loss to follow up, satisfactory compliance to protocols, however 56 participants (25.5%) withdrew from the study during treatment. Losses and reasons for losses across groups appear similar but were not examined statistically. Four who withdrew because they improved were in the intervention group and none were in the comparator group</p> <p><u>Other potential sources of bias</u> The therapist treating intervention group patients was not a McKenzie certified specialist.</p>
Garcia, 2013 ¹⁶	
<p><u>Selection bias</u> Random sequence generation A randomized sequence was created using computer generated numbers by an investigator uninvolved in treatment or assessment of patients; comparable groups were produced</p> <p>Allocation concealment Intervention allocations likely could not have been foreseen before or during enrollment. An investigator uninvolved in treatment or assessment used consecutively numbered, sealed, opaque envelopes to conceal group allocation. Envelopes were sequentially opened by the therapist following the baseline assessment of each participant</p> <p><u>Detection bias</u> Blinding of outcome assessment Blinding of outcome assessors was likely effective.</p> <p><u>Attrition bias</u> Incomplete outcome data Outcome data was complete and its handling was unlikely to have produced bias</p> <p><u>Reporting bias</u> Reporting bias Selective reporting not detected</p>	<p><u>Reporting bias</u> Selective reporting All outcomes were described in an a priori published study protocol, with planned reporting for 1, 3, and 6 month follow up. Reporting in the current study contradict the protocol. The more recent publication indicated trunk flexion range of motion was only reported at 1 month follow up.¹⁶ Study authors of the present study reported that trunk flexion range of motion was only measured at 1 month follow up "to avoid potential loss to follow-up at 3 and 6 months after randomization."¹⁶ (p.733)</p> <p><u>Performance bias</u> Blinding of participants and personnel It was not possible to blind participants and personnel (physiotherapist) to group allocation due to the nature of exercise interventions. The therapist had extensive training in both methods, but was only certified in the McKenzie Method. Thus, it is possible there was a bias toward the McKenzie Method.</p> <p>The therapist was aware of the direction of preference of all participants (important for McKenzie Method only). This may have influenced decisions regarding progression of exercises for the participants who were allocated to non-McKenzie Method group, which is by design not individually tailored.</p> <p><u>Attrition bias</u> Incomplete outcome data Compliance to home exercise sessions was not assessed</p> <p><u>Other sources of bias</u> Ecological validity The number of sessions for both groups was chosen following recommendations from the Back School method manual. The</p>

Strengths	Limitations
	<p>McKenzie Method is designed as an individually tailored intervention without a general optimal number of sessions. Authors indicated that the number of treatment sessions may be considered low for some McKenzie therapists.</p>
Non-Randomized Study	
Rosedale, 2014 ⁸	
<p><u>Selection bias</u> Random sequence generation A random sequence was created using a random number generator by an independent person and allocation was concealed until participants were enrolled and assigned to exercise or waitlist</p> <p>Allocation concealment Intervention allocations likely could not have been foreseen before or during enrollment. Opaque envelopes with group assignment were prepared by an independent person and were opened in order as patients were recruited.</p> <p><u>Detection bias</u> Blinding of outcome assessment Blinding of outcome assessor was likely effective</p>	<p><u>Selection bias</u> Random sequence generation Patients randomized to the active condition were assessed with the MDT protocol and further grouped according to diagnosis of derangement syndrome (allocated to McKenzie Method) or non-derangement/non-responder (allocated to other exercises). The composition of those with derangement syndrome in the waitlist condition is not known. At baseline, participants in the McKenzie Method group appeared to have lower intensity of pain and higher daily living pain and function issues compared with the waitlist condition, although this was not statistically analyzed.</p> <p><u>Performance bias</u> Blinding of participants and personnel Allocated interventions were known to participants and personnel during the study.</p> <p><u>Attrition bias</u> Incomplete outcome data Attrition bias due to amount and nature of incomplete outcome data. Twenty-one (17.5%) patients randomized to the MDT condition withdrew consent upon learning of their assignment, citing inability to fulfil the study commitment. Authors suggested patients did not understand commitment at time of recruitment. No baseline data were gathered at prior to withdrawal and those patients were excluded from the analysis. Compliance to the prescribed treatment programs was not measured.</p> <p><u>Reporting bias</u> Actual P values were not reported and in some cases were reported as less than or equal to 0.05, leaving the reader unable to determine statistical significance by that method. High risk of selective reporting bias due to reporting that was inconsistent with the published protocol. All outcomes measured with the KOOS scale were described prospectively as secondary outcomes. In the published study, KOOS outcomes were treated differently. Certain outcomes were further analyzed based on the type of exercise intervention received while others were not. The rationale from this deviation from the protocol is not known. Furthermore, use of the scale, the Intermittent and Constant Osteoarthritis Pain: Knee version was included in the registered protocol and not reported in the paper.</p>

KOOS = knee injury and osteoarthritis outcome score; MDT = Mechanical Diagnosis and Therapy; RCT = Randomized Controlled Trial

Appendix 4: Main Study Findings and Authors' Conclusions

Table 6: Summary of Findings Included Systematic Review and Meta-Analysis

Main Study Findings	Authors' Conclusion
Lam, 2018 ¹²	
<p>Acute low back pain</p> <ul style="list-style-type: none"> • MDT vs. "other interventions" <ul style="list-style-type: none"> <u>Pain</u> <ul style="list-style-type: none"> ○ 3 studies; MD = -0.45, 95%CI: -0.99 to 0.10, P = 0.11 <u>Disability</u> <ul style="list-style-type: none"> ○ 4 studies; MD = -0.07, 95%CI: -0.34 to 0.20, P = 0.61 • MDT vs manual therapy and exercise <ul style="list-style-type: none"> <u>Pain</u> <ul style="list-style-type: none"> ○ 2 studies; MD = -0.74, 95%CI: -1.45 to -0.03, P = 0.04 <u>Disability</u> <ul style="list-style-type: none"> ○ 3 studies; MD = -0.24, 95%CI: -0.77 to 0.28, P = 23 <p>Chronic low back pain</p> <ul style="list-style-type: none"> • MDT vs. "other interventions" <ul style="list-style-type: none"> <u>Pain</u> <ul style="list-style-type: none"> ○ 6 studies; MD = -0.33, 95%CI: -0.63 to -0.03, P = 0.03 (significant heterogeneity) <u>Disability</u> <ul style="list-style-type: none"> ○ 7 studies; MD = -0.28; MD = -0.28, 95%CI: -0.44 to -0.12, P < .01 • MDT vs. manual therapy and exercise <ul style="list-style-type: none"> <u>Pain</u> <ul style="list-style-type: none"> ○ 2 studies; MD = -0.26, 95% CI: -0.26, 95%CI: -0.73 to 0.22, P = 0.30 (significant heterogeneity) <u>Disability</u> <ul style="list-style-type: none"> ○ 3 studies; MD = -0.11, 95%CI: -0.29 to 0.07, P = 0.23 • MDT vs exercise <ul style="list-style-type: none"> <u>Pain</u> <ul style="list-style-type: none"> ○ 4 studies; MD = -0.38, 95%CI: -0.82 to 0.05, P = 0.08 (significant heterogeneity) • <u>Disability</u> <ul style="list-style-type: none"> ○ 4 studies; MD = -0.45, 95%CI: -0.64 to -0.25, P < 0.01 • MDT versus education <ul style="list-style-type: none"> <u>Pain</u> <ul style="list-style-type: none"> ○ 1 study; unable to calculate <u>Disability</u> <ul style="list-style-type: none"> ○ 1 study; unable to calculate • MDT vs. placebo <ul style="list-style-type: none"> <u>Pain</u> <ul style="list-style-type: none"> ○ 1 study; unable to calculate [See Garcia 2018] <u>Disability</u> <ul style="list-style-type: none"> ○ 1 study; unable to calculate [See Garcia 2018] 	<p><i>"There is moderate- to high quality evidence that MDT is not superior to other rehabilitation interventions for reducing pain and disability in patients with acute LBP. In patients with chronic LBP, there is moderate- to high-quality evidence that MDT is superior to other rehabilitation interventions for reducing pain and disability; however, this depends on the type of intervention being compared to MDT, and the effect sizes were generally considered small to moderate, which means clinical significance needs to be determined."</i> (p. 488)</p>

CI = Confidence Interval; LBP = low back pain; MD = mean difference; MDT = Mechanical Diagnosis and Treatment

Table 7: Summary of Findings of Included Primary Clinical Studies

Main Study Findings	Authors' Conclusion
Garcia, 2018 ¹³	
<p><u>Pain intensity (0-10)</u></p> <p>McKenzie Method vs. placebo</p> <p>5 week follow up: Unadjusted mean (SD) = 3.32 (2.75) vs. 4.18 (2.80) Adjusted MD = -1.0; CI 95%: -2.10 to -0.01, P = 0.04</p> <p>3 months: Unadjusted mean (SD) = 3.95 (2.73) vs. 4.70 (2.97) Adjusted MD = -0.94; CI 95%: -1.99 to 0.09, P = 0.07</p> <p>6 months: Unadjusted mean (SD) = 4.47 (2.84) vs. 5.03 (2.90) Adjusted MD = -0.75; CI 95%: -1.80 to 0.28, P = 0.15</p> <p>12 months: Unadjusted mean (SD) = 5.08 (3.0) vs. 4.85 (3.08) Adjusted MD = -0.07, CI 95%: -0.96 to 1.12, P = 0.88</p> <p>Secondary subgroup analyses in patients classified as derangement syndrome for pain intensity: Interaction terms (treatment by: clear centralization, pain below the knee, high pain intensity, age younger than 54 years) were not statistically significant. Data not extracted.</p> <p><u>Disability (0-24)</u></p> <p>5 week follow up: Unadjusted mean (SD) = 7.97 (6.61) vs. 9.92 (6.54) Adjusted MD = -0.84; CI 95%: -2.63 to 0.94, P = 0.35</p> <p>3 months: Unadjusted mean (SD) = 7.97 (6.32) vs. 9.85 (6.93) Adjusted MD = -0.77; CI 95%: -2.56 to 1.01, P = 0.39</p> <p>6 months: Unadjusted mean (SD) = 8.33 (7.22) vs. 9.89 (7.35) Adjusted MD = -0.45; CI 95%: -2.25 to 1.33, P = 0.61</p> <p>12 months: Unadjusted mean (SD) = 7.72 (6.87) vs. 8.48 (7.48) Adjusted MD = 0.52; CI 95%: -1.27 to 2.32, P = 0.56</p> <p>Secondary subgroup analyses in patients classified as derangement syndrome for disability: Interaction terms (treatment by: clear centralization, pain below the knee, high pain intensity, age younger than 54 years) were not statistically significant. Data not extracted.</p>	<p>“We found a small and likely not clinically relevant difference in pain intensity favouring the McKenzie MDT method immediately at the end of a 5-week treatment period. No differences were observed for the primary outcome of disability or for any other secondary outcomes (ie, function, GPE and kinesiophobia) at any follow-up times.” (p.599)</p>

Main Study Findings	Authors' Conclusion
<p><u>Function (0-10)</u></p> <p>5 week follow up: Unadjusted mean (SD) = 6.99 (2.15) vs. 6.65 (1.99) Adjusted MD = -0.18; CI 95%: -0.98 to 0.60, <i>P</i> = 0.63</p> <p>3 months: Unadjusted mean (SD) = 6.59 (1.89) vs. 5.97 (2.27) Adjusted MD = -0.46; CI 95%: -1.25 to 0.32, <i>P</i> = 0.24</p> <p>6 months: Unadjusted mean (SD) = 6.17 (2.39) vs. 5.93 (2.21) Adjusted MD = -0.08; CI 95%: -0.87 to 0.70, <i>P</i> = 0.82</p> <p>12 months: Unadjusted mean (SD) = 5.54 (2.62) vs. 6 (2.48) Adjusted MD = 0.66; CI 95%: -0.13 to 1.45, <i>P</i> = 0.10</p> <p><u>Global perceived effect (-5 to +5)</u></p> <p>5 week follow up: Unadjusted mean (SD) = 2.90 (2.64) vs. 2.53 (2.70) Adjusted MD = 0.56; CI 95%: -0.52 to 1.64, <i>P</i> = 0.31</p> <p>3 months: Unadjusted mean (SD) = 2.66 (2.37) vs. 1.92 (3.05) Adjusted MD = 0.93; CI 95%: -0.15 to 2.0, <i>P</i> = 0.09</p> <p>6 months: Unadjusted mean (SD) = 2.10 (2.86) vs. 1.63 (3.17) Adjusted MD = 0.65; CI 95%: -0.43 to 1.74, <i>P</i> = 0.23</p> <p>12 months: Unadjusted mean (SD) = 1.60 (3.0) vs. 1.30 (3.18) Adjusted MD = 0.02; CI 95%: -1.0 to 1.11, <i>P</i> = 0.95</p> <p><u>Kinesiophobia (17-68)</u></p> <p>5 week follow up: Unadjusted mean (SD) = 43.79 (8.46) vs. 48.22 (10.20) Adjusted MD = -1.28; CI 95%: -4.32 to 1.75, <i>P</i> = 0.40</p> <p>3 months: Unadjusted mean (SD) = 46.71 (9.45) vs. 48.82 (10.63) Adjusted MD = 1.02; CI 95%: -2.01 to 4.07, <i>P</i> = 0.50</p> <p>6 months: Unadjusted mean (SD) = 46.48 (9.05) vs. 47.28 (10.29) Adjusted MD = 2.25; CI 95%: -0.79 to 5.30, <i>P</i> = 0.14</p> <p>12 months: Unadjusted mean (SD) = 46.81 (12.08) vs. 48.01 (11.34) Adjusted MD = 2.01; CI 95%: -1.03 to 5.07, <i>P</i> = 0.19</p>	

Main Study Findings	Authors' Conclusion
<p><u>Adverse events</u> "Patients did not report any adverse events." (p.597)</p> <p>*Pain and disability included in the systematic review</p>	
Halliday, 2016 ¹⁴	
<p><u>Patient Specific Functional Scale (3-30)</u> Within group change = 10.56 vs. 9.93 Adjusted MD = -1.5; 95%CI: -4.15 to 1.1, <i>P</i> = 0.26</p> <p><u>Global Perceived Effect of treatment (-5 to 5)</u> Within group change = 4.3 vs. 3.6 Adjusted MD = -0.8; 95%CI: -1.5 to -0.1, <i>P</i> = 0.03</p> <p>*Pain and disability included in the systematic review</p>	<p><i>"In this population with a directional preference, we found greater improvement in perceived recovery in those receiving the McKenzie method compared to motor control exercises, but no differences in other patient-reported outcomes."</i> (p.520)</p>
Murtezani, 2015 ¹⁵	
<p><u>(Fingertip-to-floor test)</u> MDT vs. EPA Baseline: Mean score (SD) = 38.8 (11.8) vs. 38.4 (10.8); <i>P</i> = 0.66</p> <p>4-week follow-up: Mean score (SD) = 22.6 (7.4) vs. 34.2 (10.5); <i>P</i> < 0.0001</p> <p>2-month follow-up: Mean score (SD) = 16.2 (6.1) vs. 34.3 (10.4); <i>P</i> < 0.0001</p> <p>3-month follow-up: Mean score (SD) = 10.7 ± 5.7 vs. 31.6 ± 10.5; <i>P</i> < 0.0001</p>	<p><i>"In conclusion, for LBP patients McKenzie therapy does result in a greater decrease in pain and disability in the short term than do passive therapies. McKenzie therapy decreases pain, and disability, and increases spinal mobility among subjects with chronic LBP and is more effective than EPAs."</i> (p. 252)</p>
Garcia, 2013 ¹⁶	
<p><u>QoL (physical domain)</u> 1 month follow up: Unadjusted MD (SD) = 59.27 (16.88) vs. 62.45 (16.94) Adjusted MD = -3.65; 95% CI: -8.26 to 0.96, <i>P</i> = 0.12</p> <p>3 month follow up: Unadjusted MD (SD) = 57.43 (17.76) vs. 62.25 (15.37) Adjusted MD = -4.67; 95% CI: -9.26 to -0.07), <i>P</i> = 0.04</p> <p>6 month follow up: Unadjusted MD (SD) = 60.76 (18.87) vs. 61.48 (16.12) Adjusted MD = -0.44; 95% CI: -5.04 to 4.16, <i>P</i> = 0.85</p> <p><u>QoL (psychological domain)</u> 1 month follow up: Unadjusted MD (SD) = 65.12 (13.98) vs. 67.68 (15.15) Adjusted MD = -0.18; 95% CI: -4.17 to 3.80, <i>P</i> = 0.92</p> <p>3 month follow up: Unadjusted MD (SD) = 65.14 (14.14) vs. 67.62 (16.07) Adjusted MD = 0.14; 95% CI: -3.82 to 4.11, <i>P</i> = 0.94</p>	<p><i>"Patients allocated to the McKenzie group experienced greater improvements in disability, but not in pain intensity, after treatment compared with patients allocated to the Back School group, but the magnitude of this effect was small and possibly of doubtful clinical importance."</i> (p. 739)</p>

Main Study Findings	Authors' Conclusion
<p>6 month follow up: Unadjusted MD (SD) = 66.72 (14.15) vs. 68.00 (14.18) Adjusted MD = 1.50; 95% CI: -2.48 to 5.47, $P = 0.46$</p> <p><u>QoL (social domain)</u> 1 month follow up: Unadjusted MD (SD) = 67.24 (15.96) vs. 67.45 (18.00) Adjusted MD = -0.47; 95% CI: -5.50 to 4.56, $P = 0.85$</p> <p>3 month follow up: Unadjusted MD (SD) = 65.76 (16.00) vs. 69.03 (16.11) Adjusted MD = -3.15; 95% CI: -8.16 to 1.85, $P = 0.21$</p> <p>6 month follow up: Unadjusted MD (SD) = 66.09 (15.00) vs. 66.00 (18.74) Adjusted MD = 0.26; 95% CI: -4.75 to 5.28, $P = 0.91$</p> <p><u>QoL (environmental domain)</u> 1 month follow up: Unadjusted MD (SD) = 57.62 (16.48) vs. 58.57 (14.82) Adjusted MD = -0.51; 95% CI: -4.06 to 3.03, $P = 0.77$</p> <p>3 month follow up: Unadjusted MD (SD) = 56.16 (14.75) vs. 58.23 (14.65) Adjusted MD = -1.41; 95% CI: -4.94 to 2.12, $P = 0.43$</p> <p>6 month follow up: Unadjusted MD (SD) = 57.44 (15.00) vs. 57.84 (14.61) Adjusted MD = 0.29; 95% CI: -3.24 to 3.83, $P = 0.87$</p> <p><u>Range of Motion (degrees)</u> 1 month follow up: Unadjusted MD (SD) = 82.92 (18.86) vs. 80.86 (17.67) Adjusted MD = 1.42; 95% CI: -4.19 to 7.05, $P = 0.61$</p> <p><u>Adverse effects:</u> Back School: temporary exacerbation of pain in 3rd session (1 participant) McKenzie Method: No adverse effects</p>	
Non-Randomized Study	
Rosedale, 2014 ⁸	
<p><u>Pain Intensity (P4 pain scale)</u> MDT vs. exercise 2 week follow up: Adjusted MD = -8; 95%CI: -11 to -5 $d = 1.13$; 95%CI: 0.97 to 1.83 Bonferroni-corrected $P < 0.01$</p> <p>3 month follow up: Adjusted MD = -6; 95%CI: -9 to -3 $d = 0.79$; 95%CI: 0.57 to 1.40 Bonferroni-corrected $P \leq 0.05$</p>	<p><i>“In a specific population of patients with knee OA, this study found that patients benefited from either evidence based exercise or specific directional exercises that were determined by MDT assessment, compared to a wait-list control group that received no intervention. Patients classified as MDT derangement who received MDT directional exercises appear to have experienced outcomes superior to those of patients classified as MDT non-responders who received standard evidence-based exercises. It cannot be established from this study whether the difference may be attributed to the classification or the choice of therapy.” (p. 180)</i></p>

Main Study Findings	Authors' Conclusion
<p>MDT vs. waitlist 2 week follow up: Adjusted MD = -11; 95%CI: -14 to -8 d = 1.44; 95%CI: 1.34 to 2.25 P = NR</p> <p>3 month follow up: Adjusted MD = -5; 95%CI: -9 to -2 d = 0.69; 95%CI: 0.45 to 1.28 P = NR</p> <p><u>Pain in daily living (KOOS)</u></p> <p>MDT vs. exercise 2 week follow up: Adjusted MD = 13; 95%CI: 8 to 19 d = 0.98; 95%CI: 0.79 to 1.64 Bonferroni corrected $P < 0.01$</p> <p>3 month follow up: Adjusted MD = 8; 95%CI: 2 to 14 d = 0.56; 95%CI: 0.28 to 1.10 Bonferroni-corrected $P \leq 0.05$</p> <p>MDT vs. waitlist 2 week follow up: Adjusted MD = 17; 95%CI: 12 to 23 d = 1.26; 95%CI: 1.13 to 2.01 P = NR</p> <p>3 month follow up: Adjusted MD = 12; 95%CI: 6 to 18 d = 0.80; 95%CI: 0.57 to 1.41 P = NR</p> <p><u>Function in daily living (KOOS)</u></p> <p>MDT vs. exercise 2 week follow up: Adjusted MD = 12; 95%CI: 7 to 18 d = 0.89; 95%CI: 0.68 to 1.52 Bonferroni corrected $P < 0.01$</p> <p>3 month follow up: Adjusted MD = 6; 95%CI: 0 to 12 d = 0.42; 95%CI: 0.11 to 0.92 Bonferroni-corrected $P \leq 0.05$</p> <p>MDT vs. waitlist 2 week follow up: Adjusted MD = 18; 95%CI: 13 to 24 d = ; 95%CI: 1.28; 95%CI: 1.16 to 2.04 P = NR</p>	

Main Study Findings	Authors' Conclusion
3 month follow up Adjusted MD = 9; 95%CI: 3 to 15 d = 0.59; 95%CI: 0.32 to 1.15 P = NR	

CI = Confidence Interval; d = Cohen's d effect size; GPE = global perceived effect; MD = mean difference; MDT = Mechanical Diagnosis and Treatment; QoL = Quality of Life; RMDQ = Roland-Morris Disability Questionnaire; SD = Standard Deviation