Cochrane Library

Cochrane Database of Systematic Reviews

Exercise therapy for older adults with low-back pain (Protocol)

Jesus-Moraleida FR, Silva JP, Pereira DS, Domingues Dias JM, Correa Dias R, Ferreira ML, Hayden JA, Pereira LSM

Jesus-Moraleida FR, Silva JP, Pereira DS, Domingues Dias JM, Correa Dias R, Ferreira ML, Hayden JA, Pereira LSM.
Exercise therapy for older adults with low-back pain.
Cochrane Database of Systematic Reviews 2016, Issue 4. Art. No.: CD012140.
DOI: 10.1002/14651858.CD012140.

www.cochranelibrary.com

WILEY

TABLE OF CONTENTS

[Intervention Protocol]

Exercise therapy for older adults with low-back pain

Fabianna R Jesus-Moraleida[1,2], Juscelio P Silva[2], Daniele S Pereira[3], Joao Marcos Domingues Dias[2], Rosangela Correa Dias[2], Manuela L Ferreira[4], Jill A Hayden[5], Leani Souza Màximo Pereira[2]

[1]Department of Physical Therapy, Faculty of Medicine, Universidade Federal do Ceará, Fortaleza, Brazil. [2]Post Graduate Program in Rehabilitation Sciences, Department of Physical Therapy, School of Physical Education, Physical Therapy and Occupational Therapy, Universidade Federal de Minas Gerais, Belo Horizonte, Minas Gerais, Brazil. [3]Nursing school, Universidade Federal de Alfenas, Alfenas, Brazil. [4]The George Institute for Global Health & Institute of Bone and Joint Research/The Kolling Institute, Sydney Medical School, The University of Sydney, Sydney, Australia. [5]Department of Community Health & Epidemiology, Dalhousie University, Halifax, Canada

Contact address: Fabianna R Jesus-Moraleida, Department of Physical Therapy, Faculty of Medicine, Universidade Federal do Ceará, Rua Alexandre Baraúna, 949, 1o andar, Fortaleza, Ceará, 60430-160, Brazil. fabiannamoraleida@gmail.com.

Editorial group: Cochrane Back and Neck Group.
Publication status and date: New, published in Issue 4, 2016.

Citation: Jesus-Moraleida FR, Silva JP, Pereira DS, Domingues Dias JM, Correa Dias R, Ferreira ML, Hayden JA, Pereira LSM. Exercise therapy for older adults with low-back pain. *Cochrane Database of Systematic Reviews* 2016, Issue 4. Art. No.: CD012140. DOI: 10.1002/14651858.CD012140.

ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

The objective of this systematic review is to evaluate the effectiveness of exercise therapy to improve pain and/or functional performance in older people with non-specific LBP compared to no treatment and other conservative treatments.

BACKGROUND

Both developed and developing countries are experiencing a demographic transition towards an older population, resulting in a rapid increase in the prevalence of chronic, non-communicable disease-related disability (Yan 2015). Low back pain (LBP) is currently the number one cause of disability in the world, and affects approximately one fifth of the global population (Hoy 2014). Literature points to LBP lifetime prevalence that varies from 50% to 80% in the general population (Airaksinen 2006; Balague 2012). In older adults, its prevalence is extremely variable. Bressler 1999 found LBP to be common in both older men and women, with prevalence estimates varying from 6.8% to 51%. Moreover, they found that prevalence in female participants (16% to 51%) was greater than in male participants (6.8% to 49%). Current evidence shows that LBP-associated burden increases from the sixth decade (Dionne 2006; Docking 2011; Hoy 2014).

LBP in the older adult challenges healthcare systems, leading to significant social and economic costs (Gallagher 2003; Walker 2003). The condition is one of the most common reasons for seeking primary health care (Cayea 2006). Compared to other age groups, LBP in older adults is more disabling and is associated with poorer prognoses (Macfarlane 2012; Scheele 2013). Cayea 2006 reported that 36% of community-dwelling older adults aged 65 years or more are affected by at least one episode of this condition per year, of whom 21% reported moderate or intense pain. Evidence indicates that the cause of LBP in older adults is multifactorial, including both biological and psychosocial components (Rudy 2007; de Schepper 2010; Scheele 2013), and that LBP leads to a reduc-

tion in overall function and independence (Weiner 2004; Weiner 2006). Thus, proper management of this condition may have a significant impact on quality of life in the elderly.

Still, limited information is available in the literature about the effectiveness of the commonly recommended treatment approaches for the older patient with LBP. A recent systematic review revealed that 41.6% of 274 randomised controlled trials analysed excluded people aged 65 years and older, and the majority of studies included participants with mean ages younger than 65 years (Paeck 2014). These findings call into question the applicability of results found in the literature to older populations, in whom there is a higher incidence of morbidity, including frailty and osteoporosis, which can be a contraindication to some proposed treatments for low back pain. Mobility issues may also limit older adults' abilities to perform some exercises commonly prescribed for LBP (Ridda 2010). Thus, data on older adults should be analysed separately from those of the general population when considering the efficacy of exercise therapy for LBP.

Description of the condition

According to the 2006 European Guidelines (Airaksinen 2006), LBP can be defined as pain and discomfort localized below the ribs and above the gluteal crease, with or without referred leg pain. LBP can be classified as specific when the cause of pain is known, whereas non-specific pain is defined as pain without any clearly defined cause or mechanism of injury (Balague 2012). LBP can also be classified according to duration of symptoms, that is acute (up to six weeks), subacute (6 to 12 weeks), and chronic (three or more months; Airaksinen 2006).

Both clinical course and prognosis related to LBP in the general population are favourable. Acute LBP patients have a good chance of recovery, with 60% recovering in the first three months (Pengel 2003; Costa 2009; Campbell 2013). Limited information on older patients indicates that symptoms also reduce in the first months; complete recovery, however, is less likely to occur in older adults compared to the general population (Scheele 2012; Rundell 2015). Recent findings in Dutch older adults with back complaints indicated that several factors related to history and physical examination assessed at baseline were associated with worse prognosis, such as number of comorbidities, expectation of non-recovery, longer duration of symptoms, higher pain intensity at baseline, poorer performance of Timed Up and Go test, and history of back pain (Scheele 2013).

Description of the intervention

Exercise therapy is one of the most commonly used interventions for the treatment of patients with LBP. Exercise has a plausible biological rationale and low cost, and it has been recommended in most LBP clinical practice guidelines (Airaksinen 2006; Chou 2007), as well as by broad systematic reviews on this topic (Hayden 2005a; Hayden 2005b). In the current review, exercise therapy is defined as a supervised exercise program or formal and structured home exercise regimen including general physical fitness programs, back schools that include exercise prescription as a main component, aerobic exercise, and those specific techniques aimed at increasing muscle strength or stretching such as Pilates, McKenzie, Felkendrais, Tai Chi, or aquatic physiotherapy/hydrotherapy.

How the intervention might work

There is compelling evidence that therapeutic exercises have positive effects in the general population with LBP (van Middelkoop 2010). Inefficient muscle function around the spine contributes to persistence of pain in patients with LBP (Macedo 2009). Exercise therapy is known to increase strength and flexibility of the lumbar spine and its surrounding musculoskeletal structures, giving the segment proper tension to provide both movement and stability to the body (Richardson 1995). As older adults with LBP seem to have an increase of inflammatory mediators such as soluble tumour necrosis factor receptor 1 (sTNF-R1), which is related to poor functional performance (Queiroz 2014), exercise programs may have a positive effect by altering cytokine levels related to inflammation (Pereira 2013). Exercise also improves activity level, social and work participation, and coping strategies, and reduces fear-related beliefs regarding LBP (Heymans 2004; Henschke 2010), factors that seem to be clinically significant for older adults in pain (Sions 2011). Indeed, evidence indicates that this type of intervention is more effective than usual care offered by physicians for LBP complaints in adults (Hayden 2005a). While we did not identify any findings from systematic reviews or meta-analysis indicating that exercise therapy is more effective than other active or passive treatments for acute or chronic back complaints in the older patient, there is no evidence that the effects of exercise are age-specific. Therefore, similar effects would arguably be observed in the older patient.

Aging can result in significant changes in the musculoskeletal system, such as loss of muscle strength and power due to a decreased number of muscle fibres (Cruz-Jentoft 2010). These factors have a direct effect on muscle function and potentially predispose individuals to lower back injury. The frequent co-occurrence of other health conditions may also have an important impact on the choice of treatment for LBP in the older person (Klijs 2011). In one study, 98 older patients with both LBP and low bone mass significantly reduced their symptoms and disability after three types of group-training exercise therapy: resistance training, agility training, or stretch training; the first two also accounted for positive changes in perceived quality of life (Liu-Ambrose 2005).

Why it is important to do this review

Despite the fact that LBP is a significant burden for the elderly (Walker 2003; Blyth 2007), research on LBP has tended to focus on the general population with little attention given to older adults (Grotle 2005). Thus, findings from available studies may not generalize to the elderly, restricting their contribution to the treatment decision-making process for those with low back complaints. Moreover, the presence of other diseases, attitudinal barriers, and frequent medication use among this population may weigh in. Results must be clarified for elderly people with LBP, focusing on relevant outcomes. There are scientific advances in the treatment of LBP in the general population, but research on treatment effects is still quite incomplete with regard to the elderly, though there is growing interest in this field of research. By conducting a systematic review of the literature on the effect of exercise on LBP in the elderly, we will summarize the existing information on the subject to date and highlight any research gaps.

OBJECTIVES

The objective of this systematic review is to evaluate the effectiveness of exercise therapy to improve pain and/or functional performance in older people with non-specific LBP compared to no treatment and other conservative treatments.

METHODS

Criteria for considering studies for this review

Types of studies

We will include published and unpublished reports of completed randomised controlled trials.

Types of participants

We will include studies of individuals over 65 years of age who are community-dwellers, hospitalised, or in nursing homes who present with acute, subacute, or chronic non-specific LBP. When age for inclusion is not specified in the manuscript (e.g. 65 years or older), the mean (or median) age of included participants will be assessed; only trials with a majority of patients aged 65 years or older will be included. This will be achieved by including studies where the value one standard deviation less than the mean age, or the value of the first age quartile, is greater than 65 years. In those trials, we will request data from study authors about patients aged 65 years or older and will include information about this subgroup in our analyses. When no specific information on that group is available, we will perform a sensitivity analysis to investigate the influence of studies that include a mixed population of younger and older adults. Participants who present with radicular pain and other co-morbidities compatible with the aging process (e.g. knee osteoarthritis, osteoporosis, sarcopenia, or cardiovascular conditions) will be included if LBP is their main complaint. Exclusion criteria will be diagnosis of serious spinal pathology, i.e. tumour, cancer, or history of recent trauma. Studies in which 5% or more of patients have evidence of a specific clinical diagnosis for the lower back, such as spinal stenosis, will be excluded from the present investigation.

Types of interventions

For this review, we defined exercise therapy as "a series of specific movements with the aim of training or developing the body by a routine practice or as physical training to promote good physical health" (Abenhaim 2000). We will include modalities such as muscle strengthening, flexibility, stretching, aerobic exercises, general mobility exercises, and aquatic exercises. We will also include specific programs such as Pilates, Yoga, or Tai Chi, which consist of movements coordinated with controlled breathing, and McKenzie therapy, in which a set of exercises is performed according to a pre-established classification based on individual assessment. We will characterize studies according to the setting in which the intervention was performed, with or without direct supervision of a health care alliance (e.g. structured facility supervised by a healthcare provider versus video exercise protocols, respectively). Additionally, we will characterize them according to the design of the exercise program (i.e. individual or group-based exercise). Exercise therapy will be analysed alone (versus placebo or no treatment), in comparison with other forms of exercise, or in conjunction with other conservative treatments (e.g. medication, education, electrotherapy, manual therapy techniques, or acupuncture), as long as the difference between comparison groups is exercise therapy. There will be consideration of different characteristics or subgroups presented in the studies.

Types of outcome measures

For this study, we will collect information on outcomes for all periods of time assessed by the authors. We will then group them according to the following periods of follow-up assessment: short-term (up to four weeks post-randomisation), intermediate-term (six months post-randomisation) and long-term (12 months post-randomisation). When authors do not use these exact periods of assessment, we will allocate the study results according to which time period they most closely approximate, but we will limit follow-up time to two years.

Primary outcomes

We will include the following as our primary outcomes of interest.

1. Disability status specific to LBP. We will include studies measuring disability status by questionnaires or scales with evidence of validity and reliability established by the literature (e.g. the Roland Morris Disability Questionnaire and the Oswestry Disability Index; Chapman 2011), in which disability is measured by the impact that pain in the lower back has on everyday activities.

2. Functional capacity. We will include studies measuring functional capacity by instruments and test procedures recognized in the field of aging research, measuring the ability of a person to perform tasks, such as standing from a chair and walking, that are relevant at this age (e.g. gait velocity, Timed Up and Go (Pondal 2008), and general mobility tests).

3. Pain intensity. We will include studies measuring pain intensity related to the lower back using valid pain scales (e.g. the Numeric Pain Rating Scale; Childs 2005).

Secondary outcomes

Secondary outcomes will include quality of life (e.g. SF-36 and the World Health Organization Quality of Life; Castro 2014), hospitalisations (number of days in hospital), reduction of medication intake for their lower back complaint, psychological measurements (e.g. depression, kinesiophobia), adherence to exercise regimen, and global impression of recovery (e.g. Global Perceived Effect; Kamper 2010), when obtained by any reliable and valid self report measures or questionnaires.

Search methods for identification of studies

Electronic searches

We have determined that our review will be focused on a population subset of a broader systematic review on exercise for LBP (Hayden 2005). Because of this, it is appropriate to screen the results of searches already conducted for this broad review in order to identify studies for inclusion in our systematic review. We have tested the strategy to ensure that it has picked up studies already identified as relevant to our review.

The search strategy includes the following databases:

- Cochrane Back and Neck (CBN) Trials Register (via the Cochrane Central Register of Controlled Trials (CENTRAL) and/or the Cochrane Register of Studies).
- CENTRAL (via *The Cochrane Library*).
- MEDLINE (via OvidSP).
- MEDLINE In-Process & Other Non-Indexed Citations (via OvidSP).
- EMBASE (via OvidSP).
- Cumulative Index to Nursing and Allied Health Literature (CINAHL, via EBSCO).
- PsycINFO (via OvidSP).
- Physiotherapy Evidence Database (PEDro).
- SPORTDiscus (via EBSCO).
- PubMed.
- Trial registry websites: ClinicalTrials.gov and World Health Organization International Clinical Trials Registry Platform (ICTRP).

Updates to the strategy included the addition of SportDiscus and PEDro in 2007; the trials registry websites in 2011; PubMed in 2013; and MEDLINE In-Process & Other Non-Indexed Citations and the CBN Trials Register via the CRS in 2015.

In addition to screening the results from previous searches, we will use the same strategy to update the search for our review to current with no language restrictions. Search methods will be consistent with the CBN method guidelines (Furlan 2015) and the Cochrane Handbook (Higgins 2011). See Appendix 1 for the most recent and Appendix 2 for previous strategies used since the broader review.

Searching other resources

We will search the reference lists of eligible studies and relevant reviews and contact experts in the field of back pain research to identify additional trials.

Data collection and analysis

We will follow the established recommendations for both data collection and analysis in accordance with the CBN Group (Furlan 2015). We will use a standardised electronic form for each one of the phases that are included in this section.

Selection of studies

Two review authors (FRJM, JAH) will independently search for titles and abstracts that might be relevant for the review. They will then use full text papers to determine the final inclusion in the review. In the absence of agreement, a third reviewer (DSP) will decide on the inclusion of the paper based on discussion. We will exclude studies that are solely reported in conference abstracts, theses, and studies for which the full-text version is not available even after contacting the corresponding author.

Data extraction and management

Two review authors (DSP, JS) will independently extract relevant data from each of the eligible papers using a standardised data extraction form . We will extract information about the following topics.

1. Study characteristics (e.g. design, funding, authors, date of publication, language, sample size, type of allocation).

2. Characteristics of the exercise therapy (e.g. number of sessions, duration of protocol, type of exercise).

3. Population characteristics (e.g. age, gender, body mass index, severity of symptoms at baseline).
4. Comparison characteristics (e.g. inert therapy, no therapy, other exercise therapy when applicable).
5. Outcome data (type of outcome, instrument of measurement, and possible confounding factors for each specific outcome listed by authors).
6. Results of intervention (including when outcomes were assessed, e.g. immediately after the end of treatment or during follow-up).
7. Duration of follow-up assessments (e.g. short-, intermediate- and long-term follow-up measurements).
8. Funding of study/conflict of interest.
9. Reported adverse effects.

We will extract information on outcomes for both differences in score pre and post intervention and differences between groups at follow-up . We will also extract information on how clinically relevant outcomes were measured and reported and on the settings of interventions, as well as whether the effect size of the outcome is considered to be clinically relevant (van Tulder 2003; Furlan 2015).

Assessment of risk of bias in included studies

We will assess the risk of bias in included studies by using the Cochrane 'Risk of bias' tool as recommended by the Cochrane Collaboration (Higgins 2011) and the CBN Group (Furlan 2015). This risk of bias will be independently assessed by three review authors (JPS, FRJM and JPS) and disagreements between reviewers will be resolved by discussion. Each of the 13 items of the risk of bias assessment and their operational definitions are detailed in Appendix 3. These items cover the following types of bias (Furlan 2015).

1. Selection: random sequence generation, allocation concealment, group similarity at baseline.
2. Performance: blinding of participants, blinding of healthcare providers, co-interventions, and compliance.
3. Detection: blinding of outcome assessors, timing of outcome measurements.
4. Attrition: incomplete outcome data, intention-to-treat analysis.
5. Reporting: selective reporting.
6. Other sources of bias, which are not detected by the other items in the tool.

We will pilot test the assessment of risk of bias using articles that will not be appraised in the review so that review authors agree on the rationale and operationalization for the domains stated above. We will present the results of assessment and the rationale for the decisions in the 'Risk of bias tables.' Furthermore, we will use our results when grading the quality of the evidence for each primary outcome.

Measures of treatment effect

Our primary outcome measures will be disability specific to LBP, functional capacity such as gait and balance parameters, and pain. For comparison purposes, we will re-scale from 0 to 100 the outcome measures reported in the studies, if reported tests are found to be correlated. This procedure was proposed by Hayden 2005, and literature has shown that for disability, measures such as the Oswestry Disability Index and Roland Morris Disability Questionnaire are moderately to highly correlated (Leclaire 1997). Also, some measures of pain and functional capacity are known to be correlated. In the absence of reports on correlation in the literature, if outcomes have similar constructs we will pool data using standardised mean differences (SMD). Positive effect sizes will be considered a decrease of LBP-associated disability or an increase in functional capacity, that is, an increase in function. All outcomes will be reported for the periods of time stated previously in this protocol.

We expect to deal with both dichotomous and continuous outcomes in this review. Continuous outcomes will be analysed by calculating the weighted mean differences (WMD) when the same instrument is used to measure outcomes or the standardised mean differences (SMD) when different instruments are used to measure similar outcome constructs, always expressing data with 95% confidence intervals (CI). As commonly seen in studies with older patients, we also expect to encounter dichotomous outcomes such as hospitalisation and, in such cases, we will calculate the odds ratios (OR) of experiencing a positive outcome. For these outcomes, we will express the risk differences (RD) between groups. Effect sizes and 95% CI will be used as measures of treatment effect. For analysing the clinical effect in the reported outcomes, differences of 20% or more between groups will be considered clinically important for older patients with LBP, as this has been previously established for comparisons of LBP treatment in the general population (Ostelo 2008), Differences will be considered statistically different at the five percent level.

The outcome measures from the individual trials will be combined through meta-analysis where possible (comparability of population, interventions, and outcomes between trials) using a random-effects model (the DerSimonian and Laird method). If a meta-analysis is not possible, we will describe the studies and results in the text. All analyses will be conducted using Review Manager version 5 (RevMan 2008).

Unit of analysis issues

We expect to be dealing with repeated observations on participants, since studies of this nature sometimes have multiple follow-up periods. In those cases, we have defined three time points for follow-up a priori. The time points are: short-term (up to four weeks post randomisation), intermediate-term (six months post randomisation) and long-term (12 months post randomisation). As previously stated, when authors do not use one of these periods

of assessment, we will allocate outcomes to whichever time point they most closely approximate. Our methods for analysis will be guided by the outcomes selected, and we will perform separate analyses for each time point.

Dealing with missing data

When information is considered to be missing from a publication, we will first request data from authors. If data are not retrieved, we will input them with replacement values. When data are presented as a median, we will assume that value is equivalent to the mean. When data are presented as interquartile ranges, we will assume the width of the interquartile range as being equivalent to 1.35 times the standard deviation (Higgins 2011). If no standard deviation values are provided, we will calculate them from confidence intervals reported in the manuscript (if available). We will also visually estimate data from graphs if they are not presented numerically. We will perform a sensitivity analysis to investigate the impact of the stated assumptions.

Assessment of heterogeneity

According to recommendations by the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011), assessment of between-trial heterogeneity will be based upon visual inspection of the forest plot and more formally on the Chi^2 test and I^2 statistic. If I^2 is greater than 50%, we will consider it an indication that moderate heterogeneity may be present, thus we will not combine the results in a meta-analysis.

Assessment of reporting biases

Firstly, we will try to perform a broad search in order to reduce the possibility of reporting bias in our study. If reporting bias is suspected, we will try to locate the protocol for the included study to confirm whether all outcomes were reported. We will use funnel plots to evaluate publication bias (i.e. the small study effect) if we retrieve a minimum of 10 homogeneous trials reporting on the same outcome.

Data synthesis

As previously stated, we will combine results of the studies using meta-analysis. If substantial heterogeneity is present or if we retrieve few studies, we will not perform meta-analysis. If meta-analysis is not possible, we will synthesize data narratively; results from comparable trials, that is those with similar interventions and outcomes, will be described qualitatively in the text. We will produce a 'Summary of findings' table with GRADEprofiler software (GRADEpro 2014) to present results for the selected primary outcomes.

Even if there are insufficient data to allow for quantitative analyses, we will assess the overall quality of the evidence for each outcome extracted. To accomplish this, we will use the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach, as recommended in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011), and by the CBN Group (Furlan 2015). Accordingly, the domains which we will consider for judging the quality of evidence are study design, study quality, consistency, and directness (please see the definitions of these domains in Appendix 4). These analyses will be conducted for each one of the primary outcomes of the present protocol, regardless of whether a meta-analysis is conducted for it.

We will use the recommendations for classifying the levels of evidence adapted from the GRADE Working Group and defined by the CBN Group as follows (Furlan 2015).

1. High quality evidence: further research is very unlikely to change confidence in the estimate of effect.
2. Moderate quality evidence: further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.
3. Low quality evidence: further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.
4. Very low quality evidence: any estimate of effect is very uncertain.
5. No evidence: no RCTs were identified that addressed this outcome.

Following the GRADE recommendations, we will use the categories of risk of bias (limitations in the study design and implementation), inconsistency of findings (heterogeneity), indirectness (inability to generalize findings), imprecision (insufficient or imprecise data), and publication bias for all appraised studies based on Chaparro 2014 to assess the quality of the evidence. We will downgrade the quality of the evidence for a specific outcome according to the performance of the studies against these factors as follows.

1. Risk of bias: If we judge all RCTs as having a low risk of bias in the domains reported in the 'Assessment of risk of bias in included studies' section, we will not downgrade the quality of evidence. If there are three or fewer categories within the RCTs that we consider to have either high or unclear risk of bias, we will interpret that result as a serious limitation, thus we will downgrade the evidence by one level. If four or more categories for all assessed RCTs are considered to have either high or unclear risk of bias, we will interpret that result as a very serious limitation, thus we will downgrade the evidence by two levels.
2. Inconsistency of findings: If we find that there are no relevant inconsistencies between studies, unexplained heterogeneity, or variability in the results, we will not downgrade the quality of evidence.We will downgrade the quality of evidence by one level if we find that there is considerable heterogeneity or variability in the observed results (i.e. I^2 is 75% or greater; Higgins 2011). We will downgrade the quality of evidence by two levels if there is considerable heterogeneity and

variability in results or in participants, interventions, comparators, or primary outcomes.

3. Indirectness: We will downgrade the quality of evidence by one level if there is evidence that the inclusion criteria of the present systematic review differ from those of the included studies in one of these areas: participants, interventions, comparators, or primary outcomes. If there is indirectness in two or more of these areas, we will downgrade the quality of evidence by two levels.

4. Imprecision: If studies have small sample sizes or low numbers of events, this will result in wide CI around the estimate of the investigated effect which brings uncertainty to the findings. We will use the following criteria to downgrade the quality of evidence, according to the nature of the assessed outcome (i.e. dichotomous or continuous):

i) For dichotomous variables, we will downgrade the quality of evidence by one level when we find imprecision due to one of the following items, or by two levels when we find imprecision due to both of the following items.

a) There is only one study for the primary outcome or, when there is more than one study, the total number of events is less than 300 (a threshold rule-of-thumb value; Mueller 2007).

b) The 95% CI around the pooled or best estimate of effect includes both no effect and appreciable benefit or appreciable harm. The threshold for 'appreciable benefit' or 'appreciable harm' will be a relative risk reduction (RRR) or relative risk increase (RRI) greater than 25%.

ii) For continuous outcomes, we will downgrade the quality of the evidence by one level when we find imprecision due to one of the following items or by two levels when we find imprecision due to both of the following items.

a) There is only one study for the primary outcome or, when there is more than one study, the total population size is less than 400 (a threshold rule-of-thumb value; using the usual α and β, and an effect size of 0.2 standard deviations, representing a small effect).

b) The 95% CI includes no effect and the upper or lower confidence limits cross an effect size (SMD) of 0.5 in either direction.

5. Publication bias: We will downgrade the quality of the evidence by one level when funnel plots suggest the occurrence of selective publication of trials.

Subgroup analysis and investigation of heterogeneity

When it comes to systematic reviews, the existence of variability among studies is inevitable; thus, any source of variability can be called heterogeneity. Overall, heterogeneity can occur due to differences between participant characteristics, between study designs, and between interventions (Higgins 2011). Although we expect that there will not be sufficient data to perform subgroup analysis, if we retrieve a minimum of 10 studies we will explore heterogeneity by means of subgroup analysis according to these main themes.

1. Duration of symptoms (e.g. acute, subacute, chronic back pain).

2. Modality of exercise therapy (e.g. resistive training, aerobic exercise, general mobility exercise).

3. Intensity of the exercise therapy (e.g. number of sessions, duration of protocol).

4. Type of settings (e.g. home, hospital, primary care, rehabilitation centres).

5. Participant characteristics (e.g. age categories as described previously).

Sensitivity analysis

We will perform sensitivity analyses to see if the results are influenced by trials where the definition of the intervention or of LBP is not clear, where we find a mixed population (e.g. elderly and non-elderly), where treatment effects are presented as medians, or where measures of variance are missing.

ACKNOWLEDGEMENTS

Not applicable.

REFERENCES

Additional references

Abenhaim 2000

Abenhaim L, Rossignol M, Valat JP, Nordin M, Avouac B, Blotman F, et al. The role of activity in the therapeutic management of back pain. *Spine* 2000;**25**(4 Suppl):1S–33S. [PUBMED: 10707404]

Airaksinen 2006

Airaksinen O, Brox JI, Cedraschi C, Hildebrandt J, Klaber-Moffett J, Kovacs F, et al. Chapter 4. European guidelines for the management of chronic nonspecific low back pain. *European Spine Journal* 2006;**15 Suppl 2**:S192–S300.

Balague 2012

Balague F, Mannion AF, Pellise F, Cedraschi C. Non-specific low back pain. *The Lancet* 2012;**379**(9814):482–91.

Blyth 2007

Blyth F, Cumming R, Mitchell P, Wang J. Pain and falls in older people. *European Journal of Pain* 2007;**11**:564–71.

Boutron 2005
Boutron I, Moher D, Tugwell P, Giraudeau B, Poiraudeau S, Nizard R, et al. A checklist to evaluate a report of a nonpharmacological trial (CLEAR NPT) was developed using consensus. *Journal of clinical epidemiology* 2005;**58** (12):1233–40. [PUBMED: 16291467]

Bressler 1999
Bressler HB, Keyes WJ, Rochon PA, Badley E. The prevalence of low back pain in the elderly: A systematic review of the literature. *Spine* 1999;**24**:1813–9.

Campbell 2013
Campbell P, Foster NE, Thomas E, Dunn KM. Prognostic indicators of low back pain in primary care: five-year prospective study. *The Journal of Pain* 2013;**14**(8):873–83.

Castro 2014
Castro PC, Driusso P, Oishi J. Convergent validity between SF-36 and WHOQOL-BREF in older adults. *Revista Saude Publica* 2014;**48**(1):63–7. [PUBMED: 24789638]

Cayea 2006
Cayea D, Perera S, Weiner DK. Chronic low back pain in older adults: What physicians know, what they think they know, and what they should be taught. *Journal of the American Geriatric Society* 2006;**54**(11):1772–7.

Chaparro 2014
Chaparro LE, Furlan AD, Deshpande A, Mailis-Gagnon A, Atlas S, Turk DC. Opioids compared with placebo or other treatments for chronic low back pain: an update of the Cochrane Review. *Spine* 2014;**39**(7):556–63. [PUBMED: 24480962]

Chapman 2011
Chapman JR, Norvell DC, Hermsmeyer JT, Bransford RJ, DeVine J, McGirt MJ, et al. Evaluating common outcomes for measuring treatment success for chronic low back pain. *Spine* 2011;**36**(21 Suppl):S54–68. [PUBMED: 21952190]

Childs 2005
Childs JD, Piva SR, Fritz JM. Responsiveness of the numeric pain rating scale in patients with low back pain. *Spine* 2005;**30**(11):1331–4. [PUBMED: 15928561]

Chou 2007
Chou R, Qaseem A, Snow V, Casey D, Cross JT Jr, Shekelle P, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Annals of Internal Medicine* 2007;**147**(7):478–91.

Costa 2009
Costa LC, Maher CG, McAuley JH, Hancock MJ, Herbert RD, Refshauge KM, et al. Prognosis for patients with chronic low back pain: inception cohort study. *BMJ* 2009; **339**:b3829.

Cruz-Jentoft 2010
Cruz-Jentoft AJ, Baeyens JP, Bauer JM, Boirie Y, Cederholm T, Landi F, et al. Sarcopenia: European consensus on definition and diagnosis: Report of the European Working Group on Sarcopenia in Older People. *Age and Ageing* 2010 Jul;**39**(4):412–23.

de Schepper 2010
de Schepper EI, Damen J, van Meurs JB, Ginai AZ, Popham M, Hofman A, et al. The association between lumbar disc degeneration and low back pain: the influence of age, gender, and individual radiographic features. *Spine* 2010;**35** (5):531–6. [PUBMED: 20147869]

Dionne 2006
Dionne CE, Dunn KM, Croft PR. Does back pain prevalence really decrease with increasing age? A systematic review. *Age and Ageing* 2006;**35**(3):229–34.

Docking 2011
Docking RE, Fleming J, Brayne C, Zhao J, Macfarlane GJ, Jones GT. Epidemiology of back pain in older adults: prevalence and risk factors for back pain onset. *Rheumatology* 2011;**50**(9):1645–53.

Furlan 2015
Furlan AD, Malmivaara A, Chou R, Maher CG, Deyo RA, Schoene M, et al. 2015 Updated Method Guideline for Systematic Reviews in the Cochrane Back and Neck Group. *Spine* 2015;**40**(21):1660–73. [PUBMED: 26208232]

Gallagher 2003
Gallagher RM. Low back pain, health status, and quality of life in older adults: challenge and opportunity. *Pain Medicine* 2003;**4**(4):305–7.

GRADEpro 2014 [Computer program]
McMaster University. GRADEpro. McMaster University, 2014.

Grotle 2005
Grotle M, Brox JI, Veierod MB, Glomsrod B, Lonn JH, Vollestad NK. Clinical course and prognostic factors in acute low back pain: patients consulting primary care for the first time. *Spine* 2005;**30**(8):976–82.

Hayden 2005
Hayden JA, van Tulder MW, Malmivaara A, Koes BW. Exercise therapy for treatment of non-specific low back pain. *Cochrane Database of Systematic Reviews* 2005, Issue 3. [DOI: 10.1002/14651858.CD000335.pub2]

Hayden 2005a
Hayden JA, Van Tulder MW, Malmivaara AV, Koes BW. Meta-analysis: exercise therapy for nonspecific low back pain. *Annals of Internal Medicine* 2005;**142**(9):765–75.

Hayden 2005b
Hayden JA, Van Tulder MW, Tomlinson G. Systematic review: strategies for using exercise therapy to improve outcomes in chronic low back pain. *Annals of Internal Medicine* 2005;**142**(9):776–85.

Henschke 2010
Henschke N, Ostelo RW, Van Tulder MW, Vlaeyen JW, Morley S, Assendelft WJ, et al. Behavioural treatment for chronic low-back pain. *Cochrane Database of Systematic Reviews* 2010, Issue 7. [DOI: 10.1002/14651858.CD002014.pub3]

Heymans 2004
Heymans MW, Van Tulder MW, Esmail R, Bombardier C, Koes BW. Back schools for non-specific low-back pain.

Cochrane Database of Systematic Reviews 2004, Issue 4. [DOI: 10.1002/14651858.CD000261.pub2]

Higgins 2011
Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Hoy 2014
Hoy D, March L, Brooks P, Blyth F, Woolf A, Bain C, et al. The global burden of low back pain: estimates from the Global Burden of Disease. *Annals of the Rheumatic Diseases* 2014;**73**(6):968–74. [PUBMED: 24665116]

Kamper 2010
Kamper SJ, Ostelo RW, Knol DL, Maher CG, de Vet HC, Hancock MJ. Global Perceived Effect scales provided reliable assessments of health transition in people with musculoskeletal disorders, but ratings are strongly influenced by current status. *Journal of Clinical Epidemiology* 2010;**63**(7):760–6.e1. [PUBMED: 20056385]

Klijs 2011
Klijs B, Nusselder WJ, Looman CW, Mackenbach JP. Contribution of chronic disease to the burden of disability. *PLoS One* 2011;**6**(9):e25325.

Leclaire 1997
Leclaire R, Blier F, Fortin L, Proulx R. A cross-sectional study comparing the Oswestry and Roland-Morris Functional Disability scales in two populations of patients with low back pain of different levels of severity. *Spine* 1997;**22**(1):68–71. [PUBMED: 9122784]

Liu-Ambrose 2005
Liu-Ambrose TY, Khan KM, Eng JJ, Lord SR, Lentle B, McKay HA. Both resistance and agility training reduce back pain and improve health-related quality of life in older women with low bone mass. *Osteoporosis International* 2005;**16**(11):1321–9. [PUBMED: 15702262]

Macedo 2009
Macedo LG, Maher CG, Latimer J, McAuley JH. Motor control exercise for persistent, nonspecific low back pain: a systematic review. *Physical Therapy* 2009;**89**(1):9–25. [PUBMED: 19056854]

Macfarlane 2012
Macfarlane GJ, Beasley M, Jones EA, Prescott GJ, Docking R, Keeley P, et al. The prevalence and management of low back pain across adulthood: results from a population-based cross-sectional study (the MUSICIAN study). *Pain* 2012;**153**(1):27–32. [PUBMED: 21978663]

Mueller 2007
Mueller PS, Montori VM, Bassler D, Koenig BA, Guyatt GH. Ethical issues in stopping randomized trials early because of apparent benefit. *Annals of Internal Medicine* 2007;**146**(12):878–81. [PUBMED: 17577007]

Ostelo 2008
Ostelo RW, Deyo RA, Stratford P, Waddell G, Croft P, Von Korff M, et al. Interpreting change scores for pain and functional status in low back pain: towards international consensus regarding minimal important change. *Spine* 2008;**33**(1):90–4. [PUBMED: 18165753]

Paeck 2014
Paeck T, Ferreira ML, Sun C, Lin CW, Tiedemann A, Maher CG. Are older adults missing from low back pain clinical trials? A systematic review and meta-analysis. *Arthritis Care & Research* 2014;**66**(8):1220–6. [PUBMED: 24339263]

Pengel 2003
Pengel LH, Herbert RD, Maher CG, Refshauge KM. Acute low back pain: systematic review of its prognosis. *BMJ* 2003;**327**(7410):323.

Pereira 2013
Pereira DS, Mateo EC, de Queiroz BZ, Assumpcao AM, Miranda AS, Felicio DC, et al. TNF-alpha, IL6, and IL10 polymorphisms and the effect of physical exercise on inflammatory parameters and physical performance in elderly women. *Age (Dordrecht, Netherlands)* 2013;**35**(6):2455–63. [PUBMED: 23430759]

Pondal 2008
Pondal M, del Ser T. Normative data and determinants for the timed "up and go" test in a population-based sample of elderly individuals without gait disturbances. *Journal of Geriatric Physical Therapy* 2008;**31**(2):57–63. [PUBMED: 19856551]

Queiroz 2014
Queiroz BZ, Pereira DS, de Britto Rosa NM, Lopes RA, Felicio DC, Pereira DG, et al. Functional performance and plasma cytokine levels in elderly women with and without low back pain. *Journal of Back and Musculoskeletal Rehabilitation* 2015;**28**(2):343–9. [PUBMED: 25271196]

RevMan 2008 [Computer program]
The Nordic Cochrane Centre, The Cochrane Collaboration. Review Manager (RevMan). Version 5.0. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2008.

Richardson 1995
Richardson CA, Jull GA. Muscle control-pain control. What exercises would you prescribe?. *Manual Therapy* 1995;**1**:2–10.

Ridda 2010
Ridda I, MacIntyre CR, Lindley RI, Tan TC. Difficulties in recruiting older people in clinical trials: an examination of barriers and solutions. *Vaccine* 2010;**28**(4):901–6. [PUBMED: 19944149]

Rudy 2007
Rudy TE, Weiner DK, Lieber SJ, Slaboda J, Boston JR. The impact of chronic low back pain on older adults: a comparative study of patients and controls. *Pain* 2007;**131**(3):293–301.

Rundell 2015
Rundell SD, Sherman KJ, Heagerty PJ, Mock CN, Jarvik JG. The clinical course of pain and function in older adults with a new primary care visit for back pain. *Journal of the American Geriatrics Society* 2015;**63**(3):524–30. [PUBMED: 25754841]

Scheele 2012
Scheele J, Luijsterburg PA, Bierma-Zeinstra SM, Koes BW. Course of back complaints in older adults: a systematic literature review. *European Journal of Physical and Rehabilitation Medicine* 2012;**48**(3):379–86.

Scheele 2013
Scheele J, Enthoven WT, Bierma-Zeinstra SM, Peul WC, Van Tulder MW, Bohnen AM, et al. Course and prognosis of older back pain patients in general practice: a prospective cohort study. *Pain* 2013;**154**(6):951–7.

Sions 2011
Sions JM, Hicks GE. Fear-avoidance beliefs are associated with disability in older American adults with low back pain. *Physical therapy* 2011;**91**(4):525–34. [PUBMED: 21350033]

van Middelkoop 2010
van Middelkoop M, Rubinstein SM, Verhagen AP, Ostelo RW, Koes BW, Van Tulder MW. Exercise therapy for chronic nonspecific low-back pain. *Best Practice & Research: Clinical Rheumatology* 2010;**24**(2):193–204.

van Tulder 2003
van Tulder M, Furlan A, Bombardier C, Bouter L. Updated method guidelines for systematic reviews in the Cochrane Collaboration Back Review Group. *Spine* 2003;**28**(12): 1290–9. [PUBMED: 12811274]

Walker 2003
Walker BF, Muller R, Grant WD. Low back pain in Australian adults: the economic burden. *Asia-Pacific Journal of Public Health* 2003;**15**:79–87.

Weiner 2004
Weiner DK, Rudy TE, Kim YS, Golla S. Do medical factors predict disability in older adults with persistent low back pain?. *Pain* 2004;**112**(1-2):214–20.

Weiner 2006
Weiner DK, Rudy TE, Morrow L, Slaboda J, Liber S. The relationship between pain, neuropsychological performance, and physical function in community-dwelling older adults with chronic low back pain. *Pain Medicine* 2006;**7**(1): 60–70.

Yan 2015
Yan LL, Yano Y, Ye P, Yentur GK, Yip P, Yonemoto N, et al. Global, regional, and national disability-adjusted life years (DALYs) for 306 diseases and injuries and healthy life expectancy (HALE) for 188 countries, 1990-2013: quantifying the epidemiological transition. *Lancet* 2015; **386**(10009):2145–91.

* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Current search strategy

MEDLINE

Last searched January 16, 2015.

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab,ti.
5. drug therapy.fs.
6. randomly.ab,ti.
7. trial.ab,ti.
8. groups.ab,ti.
9. or/1-8
10. (animals not (humans and animals)).sh.
11. 9 not 10
12. dorsalgia.ti,ab.
13. exp Back Pain/
14. backache.ti,ab.
15. (lumbar adj pain).ti,ab.
16. coccyx.ti,ab.

17. coccydynia.ti,ab.
18. sciatica.ti,ab.
19. sciatic neuropathy/
20. spondylosis.ti,ab.
21. lumbago.ti,ab.
22. exp low back pain/
23. or/12-22
24. exp Exercise/
25. exercis$.mp.
26. physical exercis$.mp.
27. exp Exercise Therapy/
28. exp Exercise Movement Techniques/
29. exp Physical Therapy Modalities/
30. McKenzie.mp.
31. Alexander.mp.
32. William.mp.
33. feldenkrais.mp.
34. exp Yoga/
35. exp Recreation/
36. or/24-35
37. exp Alexander Disease/
38. exp Williams Syndrome/
39. 37 or 38
40. 36 not 39
41. exp Physical Fitness/
42. 40 or 41
43. 42 and 11 and 23
44. limit 43 to yr=2013-2015
45. limit 43 to ed=20131023-20150116
46. 44 or 45

MEDLINE In-Process & Other Non-Indexed Citations

Searched January 16, 2015.

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab,ti.
5. drug therapy.fs.
6. randomly.ab,ti.
7. trial.ab,ti.
8. groups.ab,ti.
9. or/1-8
10. (animals not (humans and animals)).sh.
11. 9 not 10
12. dorsalgia.ti,ab.
13. exp Back Pain/
14. backache.ti,ab.
15. (lumbar adj pain).ti,ab.
16. coccyx.ti,ab.
17. coccydynia.ti,ab.
18. sciatica.ti,ab.
19. sciatic neuropathy/

20. spondylosis.ti,ab.
21. lumbago.ti,ab.
22. exp low back pain/
23. or/12-22
24. exp Exercise/
25. exercis$.mp.
26. physical exercis$.mp.
27. exp Exercise Therapy/
28. exp Exercise Movement Techniques/
29. exp Physical Therapy Modalities/
30. McKenzie.mp.
31. Alexander.mp.
32. William.mp.
33. feldenkrais.mp.
34. exp Yoga/
35. exp Recreation/
36. or/24-35
37. exp Alexander Disease/
38. exp Williams Syndrome/
39. 37 or 38
40. 36 not 39
41. exp Physical Fitness/
42. 40 or 41
43. 42 and 11 and 23

EMBASE

Last searched January 15, 2015. Line 31 was revised in 2014 and the animal study filter was revised in 2013.

1. Clinical Article/
2. exp Clinical Study/
3. Clinical Trial/
4. Controlled Study/
5. Randomized Controlled Trial/
6. Major Clinical Study/
7. Double Blind Procedure/
8. Multicenter Study/
9. Single Blind Procedure/
10. Phase 3 Clinical Trial/
11. Phase 4 Clinical Trial/
12. crossover procedure/
13. placebo/
14. or/1-13
15. allocat$.mp.
16. assign$.mp.
17. blind$.mp.
18. (clinic$ adj25 (study or trial)).mp.
19. compar$.mp.
20. control$.mp.
21. cross?over.mp.
22. factorial$.mp.
23. follow?up.mp.
24. placebo$.mp.
25. prospectiv$.mp.

26. random$.mp.
27. ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).mp.
28. trial.mp.
29. (versus or vs).mp.
30. or/15-29
31. 14 or 30
32. exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/
33. human/ or normal human/ or human cell/
34. 32 and 33
35. 32 not 34
36. 31 not 35
37. dorsalgia.mp.
38. back pain.mp.
39. exp BACKACHE/
40. (lumbar adj pain).mp.
41. coccyx.mp.
42. coccydynia.mp.
43. sciatica.mp.
44. exp ISCHIALGIA/
45. spondylosis.mp.
46. lumbago.mp.
47. exp Low back pain/
48. back disorder$.mp.
49. or/37-48
50. exp Exercise/
51. exercis$.mp.
52. exp Kinesiotherapy/
53. physical exercise.mp.
54. exercise therapy.mp.
55. McKenzie.mp.
56. exp ALEXANDER TECHNIQUE/
57. Alexander.mp.
58. William.mp.
59. exp FELDENKRAIS METHOD/
60. Feldenkrais.mp.
61. exp YOGA/
62. yoga.mp.
63. or/50-62
64. Alexander disease.mp. or exp Alexander Disease/
65. Williams Beuren Syndrome.mp. or exp Williams Beuren Syndrome/
66. or/64-65
67. 63 not 66
68. exp FITNESS/
69. 67 or 68
70. 36 and 49 and 69
71. limit 70 to yr=2013-2015
72. limit 70 to em=201342-201502
73. 71 or 72

CENTRAL

Last searched January 16, 2015.
#1 MeSH descriptor: [Back Pain] explode all trees

#2 dorsalgia
#3 backache
#4 MeSH descriptor: [Low Back Pain] explode all trees
#5 lumbar next pain OR coccyx OR coccydynia OR sciatica OR spondylosis
#6 MeSH descriptor: [Sciatica] explode all trees
#7 MeSH descriptor: [Spine] explode all trees
#8 MeSH descriptor: [Spinal Diseases] explode all trees
#9 lumbago OR discitis OR disc near degeneration OR disc near prolapse OR disc near herniation
#10 spinal fusion
#11 spinal neoplasms
#12 facet near joints
#13 MeSH descriptor: [Intervertebral Disk] explode all trees
#14 postlaminectomy
#15 arachnoiditis
#16 failed near back
#17 MeSH descriptor: [Cauda Equina] explode all trees
#18 lumbar near vertebra*
#19 spinal near stenosis
#20 slipped near (disc* or disk*)
#21 degenerat* near (disc* or disk*)
#22 stenosis near (spine or root or spinal)
#23 displace* near (disc* or disk*)
#24 prolap* near (disc* or disk*)
#25 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24
#26 MeSH descriptor: [Exercise] explode all trees
#27 exercis*
#28 physical exercis*
#29 MeSH descriptor: [Exercise Therapy] explode all trees
#30 MeSH descriptor: [Exercise Movement Techniques] explode all trees
#31 MeSH descriptor: [Physical Therapy Modalities] explode all trees
#32 McKenzie
#33 Alexander
#34 William
#35 feldenkrais
#36 MeSH descriptor: [Yoga] explode all trees
#37 MeSH descriptor: [Recreation] explode all trees
#38 #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37
#39 MeSH descriptor: [Alexander Disease] explode all trees
#40 MeSH descriptor: [Williams Syndrome] explode all trees
#41 #39 or #40
#42 #38 not #41
#43 MeSH descriptor: [Physical Fitness] explode all trees
#44 #42 or #43
#45 #25 and #44 from 2013 to 2015, in Trials

CINAHL

Last searched January 19, 2015.
S63 S62 Limiters - Published Date: 20131001-20150131
S62 S49 and S61
S61 S50 or S51 or S52 or S53 or S54 or S55 or S56 or S57 or S58 or S59 or S60
S60 (MH "Recreation+")

S59 (“yoga”) or (MH “Yoga”)
S58 (MH “Feldenkrais Method”)
S57 (MH “Alexander Technique”)
S56 (MH “Structural-Functional-Movement Integration+”)
S55 McKenzie
S54 (MH “Therapeutic Exercise+”)
S53 (MH “Physical Therapy+”)
S52 (MH “Physical Fitness+”)
S51 (MH “Physical Activity”)
S50 (MH “Exercise+”)
S49 S28 and S48
S48 S35 or S43 or S47
S47 S44 or S45 or S46
S46 “lumbago”
S45 (MH “Spondylolisthesis”) OR (MH “Spondylolysis”)
S44 (MH “Thoracic Vertebrae”)
S43 S36 or S37 or S38 or S39 or S40 or S41 or S42
S42 lumbar N2 vertebra
S41 (MH “Lumbar Vertebrae”)
S40 “coccydynia”
S39 “coccyx”
S38 “sciatica”
S37 (MH “Sciatica”)
S36 (MH “Coccyx”)
S35 S29 or S30 or S31 or S32 or S33 or S34
S34 lumbar N5 pain
S33 lumbar W1 pain
S32 “backache”
S31 (MH “Low Back Pain”)
S30 (MH “Back Pain+”)
S29 “dorsalgia”
S28 S26 NOT S27
S27 (MH “Animals”)
S26 S7 or S12 or S19 or S25
S25 S20 or S21 or S22 or S23 or S24
S24 volunteer*
S23 prospectiv*
S22 control*
S21 followup stud*
S20 follow-up stud*
S19 S13 or S14 or S15 or S16 or S17 or S18
S18 (MH “Prospective Studies+”)
S17 (MH “Evaluation Research+”)
S16 (MH “Comparative Studies”)
S15 latin square
S14 (MH “Study Design+”)
S13 (MH “Random Sample”)
S12 S8 or S9 or S10 or S11
S11 random*
S10 placebo*
S9 (MH “Placebos”)
S8 (MH “Placebo Effect”)
S7 S1 or S2 or S3 or S4 or S5 or S6

S6 triple-blind
S5 single-blind
S4 double-blind
S3 clinical W3 trial
S2 "randomi?ed controlled trial*"
S1 (MH "Clinical Trials+")

PsycINFO

Last searched January 16, 2015.

1. clinical trials/
2. Randomi?ed controlled trial*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
3. control*.mp.
4. random*.mp.
5. exp Treatment/
6. or/1-5
7. back pain/
8. dorsalgia.mp.
9. backache.mp.
10. (lumbar adj pain).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
11. (low adj back adj pain).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
12. sciatica.mp.
13. lumbago.mp.
14. spinal nerves/
15. lumbar spinal cord/
16. ((disc or disk) adj degenerat*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
17. ((disc or disk) adj prolapse*).mp.
18. ((disc or disk) adj herniat*).mp.
19. or/7-18
20. 6 and 19
21. exp exercise/
22. exercise.mp.
23. physical fitness/
24. physical activity/
25. physical education/
26. movement therapy/
27. feldenkrais.mp.
28. alexander technique.mp.
29. or/21-28
30. 20 and 29
31. limit 30 to yr="2013-2015"

PEDro

Last searched January 15, 2015.
Therapy: Fitness training
AND
Problem: pain
AND
Body part: Lumbar spine, sacroiliac joint or pelvis
AND

Method: Clinical Trial
AND
New Records added since: 24/11/2013

SportDiscus

Last searched January 16, 2015.
S21 S16 AND S19 Limiters - Published Date: 20131001-20150131
S20 S16 AND S19
S19 S17 OR S18
S18 exercise
S17 DE "EXERCISE" or DE "BACK exercises" or DE "EXERCISE therapy" or DE "PHYSICAL education & training" or DE "PHYSICAL fitness"
S16 S10 AND S15
S15 S11 or S12 or S13 or S14
S14 DE "LUMBAR vertebrae" or DE "LUMBOSACRAL region"
S13 DE "SCIATICA"
S12 low back pain
S11 DE "BACKACHE"
S10 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9
S9 controlled clinical trial
S8 double blind
S7 randomi?ed controlled trial
S6 single blind
S5 random allocation
S4 SU randomized controlled trial
S3 SU clinical trials
S2 clinical trials
S1 placebo

ClinicalTrials.gov

Last searched January 15, 2015.
Back pain
AND
Intervention: exercise
AND
First Received from: 10/24/2013 to 01/15/2015

WHO ICTRP

Last searched January 15, 2015.
Back pain
AND
Intervention: exercise
AND
Date of registration from: 10/24/2013 to 01/15/2015

CRS

Searched January 16, 2015.
#1 ((exercise AND back pain):AB OR (exercise AND back pain):TI) AND (INREGISTER)
Selected those dated 2013 and on

Appendix 2. Previous search strategies

See Hayden 2005 for original Medline and Embase strategies

MEDLINE

April 1, 2009: the study design and animal study filter was updated from 2007
1 randomized controlled trial.pt.
2 controlled clinical trial.pt.
3 randomized.ab.
4 placebo.ab,ti.
5 drug therapy.fs.
6 randomly.ab,ti.
7 trial.ab,ti.
8 groups.ab,ti.
9 or/1-8
10 (animals not (humans and animals)).sh.
11 9 not 10
November 15, 2007 strategy:
1 exp "Clinical Trial [Publication Type]"/
2 randomized.ab,ti.
3 placebo.ab,ti.
4 dt.fs.
5 randomly.ab,ti.
6 trial.ab,ti.
7 groups.ab,ti.
8 or/1-7
9 Animals/
10 Humans/
11 9 not (9 and 10)
12 8 not 11
13 dorsalgia.ti,ab.
14 exp Back Pain/
15 backache.ti,ab.
16 (lumbar adj pain).ti,ab.
17 coccyx.ti,ab.
18 coccydynia.ti,ab.
19 sciatica.ti,ab.
20 sciatica/
21 spondylosis.ti,ab.
22 lumbago.ti,ab.
23 exp low back pain/
24 or/13-23
25 exp Exercise/
26 exercis$.mp.
27 physical exercis$.mp.
28 exp Exercise Therapy/
29 exp Exercise Movement Techniques/
30 exp Physical Therapy Modalities/
31 McKenzie.mp.
32 Alexander.mp.
33 William.mp.
34 feldenkrais.mp.

35 exp Yoga/
36 exp Recreation/
37 or/25-36
38 exp Alexander Disease/
39 exp Williams Syndrome/
40 38 or 39
41 37 not 40
42 exp Physical Fitness/
43 41 or 42
44 12 and 24 and 43
45 limit 44 to yr="2004 - 2008"

EMBASE

November 15, 2007 strategy:
1 Clinical Article/
2 exp Clinical Study/
3 Clinical Trial/
4 Controlled Study/
5 Randomized Controlled Trial/
6 Major Clinical Study/
7 Double Blind Procedure/
8 Multicenter Study/
9 Single Blind Procedure/
10 Phase 3 Clinical Trial/
11 Phase 4 Clinical Trial/
12 crossover procedure/
13 placebo/
14 or/1-13
15 allocat$.mp.
16 assign$.mp.
17 blind$.mp.
18 (clinic$ adj25 (study or trial)).mp.
19 compar$.mp.
20 control$.mp.
21 cross?over.mp.
22 factorial$.mp.
23 follow?up.mp.
24 placebo$.mp.
25 prospectiv$.mp.
26 random$.mp.
27 ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).mp.
28 trial.mp.
29 (versus or vs).mp.
30 or/15-29
31 14 and 30
32 human/
33 Nonhuman/
34 exp ANIMAL/
35 Animal Experiment/
36 33 or 34 or 35
37 32 not 36
38 31 not 36

39 37 and 38
40 38 or 39
41 dorsalgia.mp.
42 back pain.mp.
43 exp BACKACHE/
44 (lumbar adj pain).mp.
45 coccyx.mp.
46 coccydynia.mp.
47 sciatica.mp.
48 exp ISCHIALGIA/
49 spondylosis.mp.
50 lumbago.mp.
51 exp Low back pain/
52 or/41-51
53 exp Exercise/
54 exercis$.mp.
55 exp Kinesiotherapy/
56 physical exercise.mp.
57 exercise therapy.mp.
58 McKenzie.mp.
59 exp ALEXANDER TECHNIQUE/
60 Alexander.mp.
61 William.mp.
62 exp FELDENKRAIS METHOD/
63 Feldenkrais.mp.
64 exp YOGA/
65 yoga.mp.
66 or/53-65
67 Alexander disease.mp. or exp Alexander Disease/
68 Williams Beuren Syndrome.mp. or exp Williams Beuren Syndrome/
69 or/67-68
70 66 not 69
71 exp FITNESS/
72 70 or 71
73 40 and 52 and 72
74 limit 73 to yr="2004 - 2008"

CINAHL

April 1, 2009: Service provider changed to EBSCO; study design filter was updated from 2007
S55 S42 and S54 Date Range 2007-2009
S54 S43 or S44 or S45 or S46 or S47 or S48 or S49 or S50 or S51 or S52 or S53
S53 (MH "Recreation+")
S52 ("yoga") or (MH "Yoga")
S51 (MH "Feldenkrais Method")
S50 (MH "Alexander Technique")
S49 (MH "Structural-Functional-Movement Integration+")
S48 McKenzie
S47 (MH "Therapeutic Exercise+")
S46 (MH "Physical Therapy+")
S45 (MH "Physical Fitness+")
S44 (MH "Physical Activity")
S43 (MH "Exercise+")

S42 S21 and S41
S41 S40 or S39 or S38 or S37 or S36 or S35 or S34 or S33 or S32 or S31 or S30 or S29 or S28 or S27 or S26 or S25 or S24
S40 “lumbago”
S39 (MH “Spondylolysis”)
S38 (MH “Spondylolisthesis”)
S37 (MH “Thoracic Vertebrae”)
S36 (MH “Lumbar Vertebrae”)
S35 coccydynia
S34 “sciatica”
S33 “coccyx”
S32 (MH “Sciatica”)
S31 (MH “Coccyx”)
S30 “lumbar N5 pain”
S29 “”lumbarW1pain“”
S28 “lumbar W1 pain”
S27 “backache”
S26 (MH “Low Back Pain”)
S25 (MH “Back Pain+”)
S24 dorsalgia
S23 S21 not S22
S22 (MH “Animals+”)
S21 S20 or S19 or S18 or S17 or S16 or S15 or S14 or S13 or S12 or S11 or S10 or S9 or S8 or S7 or S6 or S5 or S4 or S3 or S2 or S1
S20 “volunteer*”
S19 prospectiv*
S18 “control*”
S17 “follow-up stud*”
S16 (MH “Prospective Studies+”)
S15 (MH “Evaluation Research+”)
S14 (MH “Comparative Studies”)
S13 “latin square”
S12 (MH “Study Design+”)
S11 (MH “Random Sample+”)
S10 “random*”
S9 “placebo*”
S8 (MH “Placebos”)
S7 (MH “Placebo Effect”)
S6 “triple-blind”
S5 “single-blind”
S4 “double-blind”
S3 “”clinical W8 trial“”
S2 “randomi?ed controlled trial*”
S1 (MH “Clinical Trials+”)
November 15, 2007 strategy: The service provider was Ovid
1 Randomized Controlled Trials.mp.
2 clinical trial.pt.
3 exp Clinical Trials/
4 (clin$ adj25 trial$).tw.
5 ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).tw.
6 exp PLACEBOS/
7 placebo$.tw.
8 random$.tw.
9 exp Study Design/
10 (latin adj square).tw.

11 exp Comparative Studies/
12 exp Evaluation Research/
13 Follow-Up Studies.mp.
14 exp Prospective Studies/
15 (control$ or prospectiv$ or volunteer$).tw.
16 Animals/
17 or/1-15
18 17 not 16
19 dorsalgia.ti,ab.
20 exp Back Pain/
21 backache.ti,ab.
22 (lumbar adj pain).ti,ab.
23 coccyx.ti,ab.
24 coccydynia.ti,ab.
25 sciatica.ti,ab.
26 exp SCIATICA/
27 spondylosis.ti,ab.
28 lumbago.ti,ab.
29 exp low back pain/
30 or/19-29
31 exp EXERCISE/
32 exp Physical Activity/
33 exp Physical Fitness/
34 exp Physical Therapy/
35 exp Therapeutic Exercise/
36 McKenzie.mp.
37 exp Structural-Functional-Movement Integration/
38 alexander.mp.
39 feldenkrais.mp.
40 yoga.mp. or exp YOGA/
41 exp RECREATION/
42 or/31-41
43 18 and 30 and 42
44 limit 43 to yr="2004 - 2007"

PsycINFO

October 12, 2011: The service provider changed to Ovid; strategy updated from 2007
1. clinical trials/
2. Randomi?ed controlled trial*.mp.
3. control*.mp.
4. random*.mp.
5. exp Treatment/
6. or/1-5
7. back pain/
8. dorsalgia.mp.
9. backache.mp.
10. (lumbar adj pain).mp.
11. (low adj back adj pain).mp.
12. sciatica.mp.
13. lumbago.mp.
14. spinal nerves/
15. lumbar spinal cord/

16. ((disc or disk) adj degenerat*).mp.
17. ((disc or disk) adj prolapse*).mp.
18. ((disc or disk) adj herniat*).mp.
19. or/7-18
20. 6 and 19
21. exp exercise/
22. exercise.mp.
23. physical fitness/
24. physical activity/
25. physical education/
26. movement therapy/
27. feldenkrais.mp.
28. alexander technique.mp.
29. or/21-28
30. 20 and 29
31. limit 30 to yr="2010 - 2012"
November 15, 2007 strategy: The service provider was Cambridge Scientific Abstracts (CSA)
((KW=exercise) or (DE=("exercise" or "physical activity" or "movement therapy" or "physical fitness"))) and ((KW=(Randomi?ed controlled trial*) OR KW=(clinical trial*) OR KW=(clin* near trail*) OR KW= (sing* near blind*) OR KW=(sing* near mask*) OR (doub* near blind*) OR KW=(doubl* NEAR mask*) OR KW=(trebl* near mask*) OR KW=(trebl* near mask*) OR KW=(tripl* near blind*) OR KW=(tripl* near mask*) OR KW=(placebo*) OR KW=(random*) OR DE=(research design) OR KW=(Latin square) OR KW=(comparative stud*) OR KW=(evaluation stud*) OR KW=(follow up stud*) OR DE=(prospective stud*)OR KW=(control*) OR KW=(prospective*) OR KW=(volunteer*))AND (DE=(back) OR DE=(back pain)))
Date Range: 2004 to 2008

PEDRO

November 15, 2007 strategy: The Problem field was added in 2011
Therapy: Fitness training
AND
Body part: Lumbar spine, sacroiliac joint or pelvis
AND
Published since: 2004
AND
Method: Clinical Trial

SportDiscus

November 15, 2007 strategy:
S20 S19 and S10 Limiters - Year Published from: 2004-2008
S19 S18 and S17
S18 S14 or S13 or S12 or S11
S17 S16 or S15
S16 exercise
S15 DE "EXERCISE" or DE "BACK exercises" or DE "EXERCISE therapy" or DE "PHYSICAL education & training" or DE "PHYSICAL fitness"
S14 DE "LUMBAR vertebrae" or DE "LUMBOSACRAL region"
S13 DE "SCIATICA"
S12 low back pain
S11 DE "BACKACHE"
S10 S9 or S8 or S7 or S6 or S5 or S4 or S3 or S2 or S1
S9 single blind
S8 random allocation

S7 SU randomized controlled trial
S6 SU clinical trials
S5 clinical trials
S4 placebo
S3 controlled clinical trial
S2 double blind
S1 randomi?ed controlled trial

Appendix 3. Criteria for assessing risk of bias for internal validity

Random sequence generation (selection bias)

Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence

There is a low risk of selection bias if the investigators describe a random component in the sequence generation process such as: referring to a random number table, using a computer random number generator, coin tossing, shuffling cards or envelopes, throwing dice, drawing of lots, minimisation (minimisation may be implemented without a random element, and this is considered to be equivalent to being random).
There is a high risk of selection bia*s* if the investigators describe a non-random component in the sequence generation process, such as: sequence generated by odd or even date of birth, date (or day) of admission, hospital or clinic record number; or allocation by judgement of the clinician, preference of the participant, results of a laboratory test or a series of tests, or availability of the intervention.

Allocation concealment (selection bias)

Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment

There is a low risk of selection bias if the participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: central allocation (including telephone, web-based and pharmacy-controlled randomisation); sequentially numbered drug containers of identical appearance; or sequentially numbered, opaque, sealed envelopes.
There is a high risk of bias if participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: using an open random allocation schedule (e.g. a list of random numbers); assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered); alternation or rotation; date of birth; case record number; or other explicitly unconcealed procedures.

Blinding of participants

Performance bias due to knowledge of the allocated interventions by participants during the study

There is a low risk of performance bias if blinding of participants was ensured and it was unlikely that the blinding could have been broken; or if there was no blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding.

Blinding of personnel/care providers (performance bias)

Performance bias due to knowledge of the allocated interventions by personnel/care providers during the study

There is a low risk of performance bias if blinding of personnel was ensured and it was unlikely that the blinding could have been broken; or if there was no blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding.

Blinding of outcome assessor (detection bias)

Detection bias due to knowledge of the allocated interventions by outcome assessors

There is low risk of detection bias if the blinding of the outcome assessment was ensured and it was unlikely that the blinding could have been broken; or if there was no blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding, or:

- for patient-reported outcomes in which the patient was the outcome assessor (e.g. pain, disability): there is a low risk of bias for outcome assessors if there is a low risk of bias for participant blinding (Boutron 2005)
- for outcome criteria that are clinical or therapeutic events that will be determined by the interaction between patients and care providers (e.g. co-interventions, length of hospitalisation, treatment failure), in which the care provider is the outcome assessor: there is a low risk of bias for outcome assessors if there is a low risk of bias for care providers (Boutron 2005)
- for outcome criteria that are assessed from data from medical forms: there is a low risk of bias if the treatment or adverse effects of the treatment could not be noticed in the extracted data (Boutron 2005)

Incomplete outcome data (attrition bias)

Attrition bias due to amount, nature, or handling of incomplete outcome data

There is a low risk of attrition bias if there were no missing outcome data; reasons for missing outcome data were unlikely to be related to the true outcome (for survival data, censoring unlikely to be introducing bias); missing outcome data were balanced in numbers, with similar reasons for missing data across groups; for dichotomous outcome data, the proportion of missing outcomes compared with the observed event risk was not enough to have a clinically relevant impact on the intervention effect estimate; for continuous outcome data, the plausible effect size (difference in means or standardised difference in means) among missing outcomes was not enough to have a clinically relevant impact on observed effect size, or missing data were imputed using appropriate methods (if drop-outs are very large, imputation using even "acceptable" methods may still suggest a high risk of bias; van Tulder 2003). The percentage of withdrawals and drop-outs should not exceed 20% for short-term follow-up and 30% for long-term follow-up and should not lead to substantial bias (these percentages are commonly used but arbitrary, not supported by literature; van Tulder 2003).

Selective reporting (reporting bias)

Reporting bias due to selective outcome reporting

There is low risk of reporting bias if the study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way, or if the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).

There is a high risk of reporting bias if not all of the study's pre-specified primary outcomes have been reported; one or more primary outcomes is reported using measurements, analysis methods, or subsets of the data (e.g. sub scales) that were not pre-specified; any of the reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); one or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; or the study report fails to include results for a key outcome that would be expected to have been reported for such a study.

Group similarity at baseline (selection bias)

Bias due to dissimilarity at baseline for the most important prognostic indicators

There is low risk of bia*s* if groups are similar at baseline for demographic factors, value of main outcome measure(s), and important prognostic factors (examples in the field of back and neck pain are duration and severity of complaints, vocational status, and percentage of patients with neurological symptoms; van Tulder 2003).

Co-interventions (performance bias)

Bias because co-interventions were different across groups

There is low risk of bias if there were no co-interventions or they were similar between the index and control groups (van Tulder 2003).

Compliance (performance bias)

Bias due to inappropriate compliance with interventions across groups

There is low risk of bias if compliance with the interventions was acceptable based on the reported intensity/dosage, duration, number, and frequency for both the index and control interventions. For single-session interventions (e.g. surgery), this item is irrelevant (van Tulder 2003).

Intention-to-treat-analysis (attrition bias)

There is low risk of bias if all randomised patients were reported/analysed in the group to which they were allocated by randomisation.

Timing of outcome assessments (detection bias)

Bias because important outcomes were not measured at the same time across groups

There is low risk of bias if all important outcome assessments for all intervention groups were measured at the same time (van Tulder 2003).

Other bias

Bias due to problems not covered elsewhere in the table

There is a low risk of bias if the study appears to be free of other sources of bias not addressed elsewhere (e.g. study funding).

Appendix 4. Definitions of the GRADE domains used for evidence synthesis

1. **Study design**: refers to the design of the analysed study. We will only included randomised controlled trials in this review (Higgins 2011).
2.**Study quality**: refers to the detailed methods and implementation section from the analysed study (Higgins 2011).
3. **Consistency**: refers to the similarity of estimates of effect across studies (Higgins 2011).
4. **Directness**: refers to the extent to which the people, interventions, and outcome measures are similar to those of interest (Higgins 2011).

CONTRIBUTIONS OF AUTHORS

Conception, design, and drafting of the protocol: Fabianna R. Jesus-Moraleida, Juscélio Silva, Daniele Pereira, Joao Marcos Domingues Dias, Rosangela Correa Dias, Leani Souza Máximo Pereira

Critical revision of the protocol: Manuela L. Ferreira and Jill A. Hayden.

Final approval of the protocol: all authors.

DECLARATIONS OF INTEREST

All authors except J.A.H. are currently enrolled in the Back Complaints in the Elders international consortium that aims to assess the burden of back pain in older adults.

SOURCES OF SUPPORT

Internal sources

- None, Other.

External sources

- None, Other.