RISK FACTORS AND CONTEMPORARY MANAGEMENT OF LOW BACK PAIN

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BPhty (Hons)

A thesis submitted in fulfillment of the requirements for the degree of

Doctor of Philosophy

Sydney School of Public Health, Sydney Medical School

The University of Sydney

2018

Supervisors' statement

As supervisors of Patrícia do Carmo Silva Parreira's doctoral work, we certify that we consider her thesis "Risk factors and contemporary management of low back pain" to be suitable for examination.

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Candidate's statement

I, Patrícia do Carmo Silva Parreira, certify that the intellectual content of this thesis is the product of my own work and that all the assistance received in preparing this thesis and sources have been acknowledged. It does not contain any material previously published or written by another person. This thesis has not been submitted for any degree or other purposes.

I, Patrícia do Carmo Silva Parreira, understand that if I am awarded a higher degree for my thesis entitled "Risk factors and contemporary management of low back pain" being lodged herewith for examination, the thesis will be lodged in The University of Sydney library and be available immediately for use. I agree that the University Librarian (or in the case of a department, the Head of the Department) may supply photocopy or microform of the thesis to an individual for research or study or to a library.

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Patrícia do Carmo Silva Parreira Date: 08/07/2018

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Acknowledgements

Chris and Manuela, there are no words to describe my gratitude. You were the best supervisors and I was so lucky to work closely with you during these past years. My PhD was a wonderful and enjoyable experience because of your patience, friendship and knowledge. I will never forget this experience.

I also would like to acknowledge two special people that made this dream possible. Leo and Lu, you were the best mentors I could ever had. Thank you so much and I will be always grateful for everything you did for me.

To the Musculoskeletal Health Sydney, it was amazing to work with every one of you. Steve and Adrian, a huge thank you for the many times you reviewed my papers and presentations. Anne Moseley, thank you for the opportunity to work with PEDro. For all my researcher mates, thank you for making this journey much more enjoyable. Thank you Daniel, Marina, Gustavo, Tie, Bruno, Marcinha, Zambelli, Steph, Mike, Aron, Matt, Christina, Amabile, Amanda, Rodrigo, Daniel, Tarci, Ana Paula, Crystian and many others. I will never forget the great time we spent together and I do hope our friendships will extend well beyond our shared time in Sydney.

To my Australian family: Anita, Dani, Karla, Juliana, Marina, Nayara, Paula, Polyana and Tatiane. Thank you for all your support. You guys are amazing and I am blessed to have you all around me. To all my friends in Brazil, I love you guys, thank you for your support and friendship – we will celebrate together soon. In particular, Paula Marreiros, thank you for all your help and for being such a good friend.

To my family in Brazil, I thank you for your support and love. In special, I would like to express my appreciation to my parents Nilze and Jose, my siblings Luiz Eduardo, Ana Paula and Luiz Fernando, my sister-in-law Priscila and my dearest nephews and nieces Eduardo, Barbara, Pedro, Gabriel, Camila and Giovana. You are the best family I could ever have, a never-ending source of strength and energy in my life. This thesis is dedicated to you!

I would like to show my appreciation to CAPES for providing me with financial support over the course of my PhD.

Publications and Presentations

Parts of the work presented in this thesis have been published or submitted to a peer-reviewed journal and presented in national and international conferences.

Published or accepted papers

1. **Parreira P**.; Heymans M.; Van Tulder M.; Esmail R.; Poquet N.; Lin CC.; Maher CG. Back School for chronic: a systematic review protocol. Cochrane Database of Systematic Reviews 2015, Issue 5. Art. No.: CD011674
2. **Parreira P**.; Maher CG; Latimer J.; Steffens D.; Blyth F.; Li Q.; Ferreira ML. Can patients identify what triggers their back pain? Secondary analysis of a case-crossover study. Pain. 2015 Oct; 156(10):1913-9.
3. **Parreira P.**; Maher CG; Ferreira ML. Effect of education on non-specific neck and low back pain: A meta-analysis of randomized controlled trials. Man Ther. 2016 Mar 24. pii: S1356-689X(16)00034-5. doi: 10.1016
4. **Parreira P**, Heymans MW, van Tulder MW, Esmail R, Koes BW, Poquet N, Lin CC, Maher CG. Back Schools for chronic non-specific low back pain. Cochrane Database Systematic Reviews. 2017 Aug 3; 8:CD011674
5. **Parreira P**.; Maher CG; Megale RM; Ferreira FL. An overview of clinical guidelines for the management of vertebral compression fracture: A systematic review. Spine J 2017 Jul; S1529-9430(17)30495-3.
6. **Parreira P**, Maher CG, Ferreira ML, Machado GC, Blyth FM, Naganathan V, Waite LM, Seibel MJ, Handelsman D, Cumming RG. A longitudinal study of the influence of comorbidities and lifestyle factors on low back pain in older men. Pain. 2017 Aug;158(8):1571-1576

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Submitted papers

1. Parreira P.; Maher CG.; Downie A; Traeger A; Hancock M.; Ferreira ML Evolution, and consistency between guidelines, of guideline-endorsed red flags for fracture in patients presenting with LBP. Submitted to British Journal of Sports Medicine.

Presentations

1. *Oral presentation*- Kinesio Taping to generate skin convolutions is not better than sham taping for people with chronic non-specific low back pain: a randomised trial. Proceedings of the XIII International Back Pain Forum, 2014 September 30 to October 3; Campos do Jordao, Sao Paulo, Brazil.
2. *Oral presentation*- Can patients identify what triggers their back pain? Secondary analysis of a case-crossover study. Proceedings of the World Confederation for Physical Therapy Congress; 2015 May 1 to 4, Singapore.
3. *Oral presentation*- Can patients identify what triggers their back pain? Secondary analysis of a case-crossover study. Proceedings of the School of Public Health Conference; 2015 December 10, Sydney, New South Wales, Australia.
4. *Poster presentation*- A longitudinal study of the influence of comorbidities and lifestyle factors on low back pain in older men. Proceedings of the XIV International Back and Neck Pain Forum; 2016 May 31 to June 3, Buxton, Derbyshire, United Kingdom.

5. *Oral presentation*- Risk factors for low back pain and sciatica: An umbrella review. Proceedings of the Musculoskeletal Health Sydney- School of Public Health; 2017 August 17, Sydney, New South Wales, Australia.
6. *Oral presentation*- Risk factors for low back pain and sciatica: An umbrella review. Proceedings of the XV International Back Pain Forum; 2017 September 12 to 15; Oslo, Norway.

Preface

The chapters included in this thesis comprise six individual studies investigating risk factors and contemporary management of low back pain. The University of Sydney allows published papers that arose from the candidature to be included in the thesis. Chapters, three, four, five and six are the PDF files of the publication, while chapters two and seven are the submitted manuscripts.

Chapter One is the introduction to the thesis and provides an overview of the relevant literature regarding epidemiology, contemporary management and mechanisms, and outcome response in low back pain.

Chapter Two is an umbrella review investigating risk factors for a future episode of LBP and sciatica. This study is presented as published in *The Spine Journal*. The registered protocol for this study is presented in Appendix A.

Chapter Three is a case-crossover study investigating the extent to which patients can accurately nominate what has triggered their new episode of sudden onset, acute LBP. This study is presented as published in *Pain.*

Chapter Four is a cohort study investigating the course of LBP in older men, if comorbidities/ lifestyle factors can predict the course of LBP in older men and if comorbidities/ lifestyle can increase the risk of developing LBP in older men. This study is presented as published in *Pain.*

Chapter Five is a Cochrane systematic review investigating the effectiveness of Back Schools for low back pain and is presented as published in the *Cochrane Database of Systematic Reviews*. The published protocol for this study is presented in Appendix B.

Chapter Six consists of a systematic review to appraising the recommendations and methodological quality of international clinical guidelines for the management of vertebral compression fracture. This study is presented as published in *The Spine Journal.* The registered protocol for this study is presented in Appendix C.

Chapter Seven consists of a systematic review describing the evolution of guideline-endorsed red flags for fracture in patients presenting with low back pain and to evaluating consistency between them. The study in this chapter is presented in the format required by the *British Journal of Sports Medicine* where it has been submitted for publication. The registered protocol for this study is presented in Appendix D.

Finally, **Chapter Eight** consists of an overview, and discusses the clinical implications and directions for further research. Each chapter contains its own reference list. Appendices that were published as online supplementary material are included at the end of the relevant chapter.

Abstract

The broad aim of this thesis was to contribute to a better understanding of the mechanisms and management of non-specific low back pain (LBP) by investigating treatment options, mechanisms and outcomes. **Chapter Two** provides an overview of risk factors for LBP in an umbrella review of the evidence revealing that individual, biomechanical and psychosocial factors increase risk for a future episode of LBP and sciatica. The study presented in **Chapter Three** aimed to investigate the extent to which patients can accurately nominate what has triggered their new episode of sudden onset, acute LBP. This study provides evidence that patients can clearly identify an activity that triggered their sudden-onset acute LBP. **Chapter Four** is a cohort study investigating the course of LBP in older men, if comorbidities/ lifestyle factors can predict the course of LBP in older men and if comorbidities/ lifestyle can increase the risk of developing LBP in older men. Two years after entering the study, older men continued to experience pain. Also, the higher number of comorbidities increased the odds of developing LBP and lifestyle factors influenced its course. **Chapter Five** investigated the effect of Back School on pain and disability for adults with chronic non-specific LBP in a Cochrane systematic review. Regardless of the comparison used (as well as the outcomes investigated), the results of the meta-analysis shows no difference or a trivial effect in favour of the Back School intervention. **Chapter Six** appraised the recommendations and methodological quality of international clinical guidelines for the management of vertebral compression fractures. The comparison of clinical guidelines for the management of vertebral compression fractures shows that diagnostic and therapeutic recommendations are generally inconsistent. The evidence available to guideline developers is limited in quantity and quality. **Chapter Seven** described the evolution of guideline-endorsed red flags for fracture in patients presenting with LBP and described the consistency between guidelines in the endorsement of red flags for fracture. The results shows that the

number of red flags endorsed in guidelines to screen for fracture has risen over time; most guidelines do not endorse the same set of red flags and most recommendations are not supported by research or accompanied by diagnostic accuracy data. The studies in this thesis have provided an important contribution to the understanding of contemporary management of LBP. The main implications are: i) individual, biomechanical and psychosocial factors increase risk for a future episode of LBP and sciatica.; ii) patients can accurately nominate an activity that triggered their sudden-onset acute LBP: iii) LBP is typically persistent in older men and a higher number of comorbidities increased the odds of developing LBP; and lifestyle factors such as higher BMI and higher consumption of alcohol influenced its course iv) Back Schools showed no difference or a trivial effect for chronic LBP regardless of the comparison used v) Recommendations in clinical practice guidelines on vertebral compression fractures interventions should be reviewed vi) The number of red flags endorsed in guidelines to screen for fracture has risen over the years; most guidelines do not endorse the same set of red flags.

Chapter One

Introduction

1.1. Introduction to low back pain

Low back pain can be defined as pain or discomfort below the ribs and above the gluteal crease, with or without leg symptoms[1]. It remains a common condition with an estimated lifetime prevalence of approximately 80%[1 3]. Along with the high prevalence and burden on individuals, the direct and indirect costs associated with low back pain are substantial and it is a leading cause of activity limitation and work absence throughout much of the world. The condition is the leading cause of disability burden expressed as years lived with disability[2].

1.2. Classification of low back pain

Low back pain is often classified using a diagnostic triage approach that includes three categories: serious spinal pathology, nerve root compromise/spinal canal stenosis and non-specific low back pain [1 3]. In primary care ~90-95% of patients with low back pain will have "non-specific low back pain", when the anatomical structure causing the pain cannot be identified[1]. Non-specific low back pain is generally classified into three stages according to the duration of symptoms (acute, subacute and chronic). Acute low back pain is usually defined as an episode of pain that persists for less than six weeks, episodes lasting 6 to 12 weeks are classified as subacute and episodes lasting more than 12 weeks are classified as chronic[1]. Of the remaining patients, ~ 1% have a serious spinal pathology as the cause of their low back pain (e.g. cancer, infection, fracture, or inflammatory process), and about 5% some type of neurologic compromise, where sciatica and lumbar spinal stenosis are the most common diagnoses[1 3,7,4]. This classification is extremely important to assist health professionals in determining the 11prognosis, as well as providing adequate treatment alternatives for their patients[5].

1.3. Risk and prognosis factors for low back pain

1.3.1. Risk factors

A variety of environmental and individual characteristics has been reported to increase the risk of an episode of low back pain and sciatica [6 7]. These factors can be aggregated into categories including characteristics of the individual (such as age and gender), physical stress on the spine (such as regular lifting and whole body vibration), poor general health (such as smoking and obesity) and psychological stress (monotonous work and depression)[8].

Identifying factors that may increase the risk for, or predispose individuals to, the development of back pain and sciatica is critical in attempting to reduce the prevalence and ultimately to decrease the social impact of this condition[8]. A better understanding of risk factors for low back pain and sciatica provides a logical rationale, which is currently lacking, for the development of more effective prevention strategies. Numerous systematic reviews and meta-analyses of risk factors associated with low back pain and sciatica have been published[7 9-11] but they are limited either due to methodological weaknesses or because they only consider a subset of potential risk factors. Therefore, to provide an overview of the evidence on all risk factors for low back pain and sciatica, the umbrella review in **Chapter Two** summarises and appraises the evidence from existing systematic reviews.

1.3.1.1. Patients' views on risk factors for low back pain

Patients' ability to identify risk factors for low back pain is probably informed by their life experiences including previous experience of low back pain, their education and beliefs, and work-site training[12 13]. Understanding patients' views strengthens support for previously identified risk factors and highlights other relevant risk factors not previously considered as risk factors[14]. Recently, research into patients' views regarding factors that trigger an episode of low back pain has been conducted using qualitative methods. However, these results are

based on expectations and beliefs about the causes of low back pain. Should it be demonstrated that patients can accurately identify these risk factors then clinicians could apply this information when developing individual treatment and prevention programs. **Chapter Three** is the published manuscript of a case-crossover study investigating the extent to which patients can accurately nominate what has triggered their new episode of sudden onset, acute low back pain.

1.3.2. Prognostic factors

Prognosis is a prediction of the outcome of a health condition over time[15]. Numerous prognostic factors have been reported for low back pain, with some associated with worse outcomes and others with a better outcome. Prognostic factors are associated to the back pain episode, the individual and psychological characteristics, as well as the work and social environment[15 16].

The likely prognosis of low back pain varies according to the duration of symptoms[16]. Patients with acute non-specific low back pain usually demonstrate a favourable prognosis with significant improvement within the first six weeks. After that, the improvement rates slow down and approximately 40% of patients are likely to develop chronic non-specific low back pain[16]. Understanding the prognostic factors for a condition assists in the identification of people who are less likely to recover.

1.4. Risk and prognosis factors in older adults with low back pain

Back pain is the most common type of pain reported by older adults aged 65 years and over[17]. Despite the high prevalence, older adults are largely under-represented[18] in back pain research. Usually, patients aged >60 or 65 years are excluded from studies[19] in the back pain field. In consequence, little is known about risk factors for developing low back pain, or the

course and prognostic factors for low back pain in older adults. It is also likely that clinicians assess and treat older patients based on evidence from studies of the younger population[20]. The degree to which research on young adults is generalisable to older adults is questionable, as there are differences between these populations including associated comorbidities, lifestyle and economic factors[21].

Lifestyle behaviours and comorbidities both impact health outcomes and are associated with the development or progression of common chronic conditions[22-24]. Several studies have shown that some lifestyle behaviours, such as smoking and physical inactivity, are associated with cardiovascular or diabetes mellitus[22-24]. Consideration of comorbidities is more complex due to the interaction between disease states. In general, it is known that the number of health comorbidities increases substantially with age and is associated with an increase in bodily pain and more limitations in activities of daily living[23 25]. While the association between lifestyle factors and comorbidities has been explored for some disease states[23], few data exist on the effect of these factors on course, prognostic and risk factors for low back pain in older adults. To address this gap in the literature **Chapter Four** presents a published manuscript evaluating the course, risk factors and prognostic factors for older men participating in the CHAMP cohort study.

1.5. Management of low back pain

1.5.1. Non-specific low back pain

In order to improve treatment outcomes, clinical practice guidelines have been developed in many countries[26-28]. Clinical practice guidelines can be potent tools for helping evidence-based practice, as they incorporate research findings in order to support decision-making.

These guidelines have been expected to facilitate more consistent, effective and efficient medical practice, and ultimately improve health outcomes.

Overall, clinical practice guidelines endorse similar management strategies for non-specific low back pain. A systematic review of clinical practice guidelines[29] assessed the available clinical guidelines from 13 countries. The conclusion was that the guidelines provided generally similar recommendations regarding the diagnostic classification and the use of diagnostic and therapeutic interventions. Consistent features were the early and gradual activation of patients, the discouragement of prescribed bed rest, and the recognition of psychosocial factors as risk factors for chronicity.

For patients with chronic non-specific low back pain, a wide variety of therapeutic possibilities are available. These treatments range from educational programs, through cognitive behavioral therapy, medications, electrophysical agents (TENS, laser), manual therapy, exercise and others. Between all these intervention possibilities, supervised exercise therapy[1 30] associated with an educational component[31] has been considered as one of the most effective interventions in reducing pain and disability in patients with chronic non-specific low back pain[1 30 31]. Education has been recommended in clinical practice guidelines for chronic low back pain[1] and according to previous studies, exercise therapy is commonly advised for people with low back pain, and it is recommended in clinical practice guidelines as an effective treatment for chronic low back pain[1]. A Cochrane systematic review on this topic also concluded that exercise therapy is effective in decreasing pain and improving function in adults with chronic low back pain[32].

Although the recommendations from clinical practice guidelines rarely included information about Back School, this method is an active therapy option that includes both exercises and education for the treatment of patients with chronic low back pain[33 34]. The original Swedish Back School program included information on the anatomy of the back, biomechanics, optimal posture, ergonomics, and back exercises. The lessons are given to groups of patients supervised by a physical therapist or medical specialist. The sessions are scheduled during a two-week period, and each session lasts 45 minutes. Since the introduction of the Swedish Back School, the content and length of the method have changed and appear to vary widely today. While the Back School method has been investigated in randomised controlled trials, there was a need to appraise and synthesise these trial results in a high-quality systematic review with meta-analysis. Therefore, a rigorous systematic review using the Cochrane methodology is required. C**hapter Five** of this thesis presents a published Cochrane systematic review evaluating the effectiveness of Back schools for chronic non-specific low back pain.

1.5.2. Serious spinal pathology

Though serious spinal pathologies associated with low back pain are infrequent, it is suggested that all patients presenting with low back pain should be screened for these conditions during the clinical examination[35]. In the primary care setting, guidelines recommend the use of red flags to screen for serious pathology[36 37]. Red flags are features from a clinical history or physical examination that are believed to increase the probability of serious disease in a given patient[37].

The most common of these serious pathologies in a primary care setting is vertebral fracture[37 38]. Symptomatic vertebral fractures often lead to severe spinal pain, spinal deformity [39 40],

decreased mobility [39 40], and decreased pulmonary function [39 40] and can increase the risk of age-adjusted mortality[39 40]. To identify an increased risk of vertebral fracture, clinical guidelines generally recommend assessing some red flags, such as a recent history of trauma and prolonged use of corticosteroids[38]. However, most guidelines do not endorse the same set of red flags, there is no information on diagnostic accuracy of the endorsed red flags and the recommendations regarding further diagnostic work-up vary between them. This inconsistency creates uncertainty for clinicians managing these patients [25,26.]. The lack of consensus in vertebral fractures management means that clinicians must rely on their own expertise when managing patients with symptomatic vertebral fractures, resulting in significant variation in usual care.

This scenario points to the urgent need for improved understanding of red flags in screening vertebral fracture and informing the management of this condition. The study presented in the **Chapter Six** seeks to compare the content of international clinical guidelines for the management of vertebral fractures and also appraised the methodological quality of included guidelines. **Chapter Seven** describes the evolution of guideline-endorsed red flags for fracture in patients presenting with low back pain and to evaluate consistency between them.

1.6. Aims of the thesis:

The aims of this thesis were to:

1. Provide an overview of risk factors for low back pain (Chapter Two).
2. Investigate the extent to which patients can accurately nominate what has triggered their new episode of sudden onset, acute low back pain (Chapter Three).

3. Describe the course of low back pain in older men over 2 years and investigate if the presence of comorbidities or lifestyle factors can predict the course of low back pain or can increase the risk of developing low back pain in older men (Chapter Four).
4. Determine the effect of Back School on pain and disability for adults with chronic non-specific low back pain (Chapter Five).
5. Present and compare the content of international clinical guidelines for the management of vertebral compression fractures and also appraise the methodological quality of included guidelines (Chapter Six).
6. Describe the evolution of guideline-endorsed red flags for fracture in patients presenting with low back pain and to evaluate consistency between them (Chapter Seven).

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.

Chapter Two

Risk factors for low back pain and sciatica: An umbrella review

Chapter Two has been presented as:

Parreira PCS, Maher CG, Steffens D, Hancock M, Ferreira ML. *Risk factors for low back pain and sciatica: An umbrella review*. *Spine J 2018 May; pii: S1529-9430(18)30243-2. doi: 10.1016/j.spinee.2018.05.018. [Epub ahead of print]*.

Statement from co-authors confirming authorship contribution of the PhD candidate

The co-authors of the paper: "*Parreira PCS, Maher CG, Steffens D, Hancock M, Ferreira ML. Risk factors for low back pain and sciatica: An umbrella review*" 1.Spine J 2018 May; pii: S1529-9430(18)30243-2. doi: 10.1016/j.spinee.2018.05.018. [Epub ahead of print] confirm that Patricia C S Parreira has made the primary contribution to this study in each of the following areas:

• Conception and design of the research

• Interpretation of findings

• Writing of the manuscript and critical appraisal of content

In addition to the statements above, in cases where I am not the corresponding author of a published item, permission to include the published material has been granted by the corresponding author.

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ELSEVIER

The Spine Journal ■■ (2018) ■■–■■

THE SPINE JOURNAL

Review Article

Risk factors for low back pain and sciatica: an umbrella review

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Received 29 September 2017; revised 1 May 2018; accepted 16 May 2018

Abstract

BACKGROUND: Low back pain (LBP) is a highly prevalent condition and it is associated with significant disability and work absenteeism worldwide. A variety of environmental and individual characteristics have been reported to increase the risk of LBP. To our knowledge, there has been no previous attempt to summarize the evidence from existing systematic reviews of risk factors for LBP or sciatica.

PURPOSE: To provide an overview of risk factors for LBP, we completed an umbrella review of the evidence from existing systematic reviews.

STUDY DESIGN: An umbrella review was carried out.

METHODS: A systematic literature search was conducted in MEDLINE, EMBASE, PubMed PsychINFO, and CINAHL databases. To focus on the most recent evidence, we only included systematic reviews published in the last 5 years (2011–2016) examining any risk factor for LBP or sciatica. Only systematic reviews of cohort studies enrolling participants without LBP and sciatica at baseline were included. The methodological quality of the reviews was assessed independently by two review authors, using the Assessment of Multiple Systematic Reviews tool.

RESULTS: We included 15 systematic reviews containing 134 cohort studies. Four systematic reviews were of high methodological quality and 11 were of moderate quality. Of the 54 risk factors investigated, 38 risk factors were significantly associated with increased risk of LBP or sciatica in at least one systematic review and the odds ratios ranged from 1.26 to 13.00. Adverse risk factors included characteristics of the individual (eg, older age), poor general health (eg, smoking), physical stress on spine (eg, vibration), and psychological stress (eg, depression).

CONCLUSION: Poor general health, physical and psychological stress, and characteristics of the person increase risk for a future episode of LBP or sciatica.

Keywords: Cohort studies; Low back pain; Risk factors; Sciatica; Systematic review; Umbrella review

FDA device/drug status: Not applicable.

Author disclosures: ***PP:*** Nothing to disclose. ***CGM***: Nothing to disclose. ***DS:*** Nothing to disclose. ***MH:*** Nothing to disclose. ***MLF:*** Nothing to disclose.

The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

Patricia C.S. Parreira is supported by CAPES (Coordenação de Aperfeiçoamento de Pessoal de Nível Superior), Brazil. Chris G. Maher is supported by the National Health and Medical Research Council of Australia. Manuela L. Ferreira is supported by the National Health and Medical Research Council of Australia.

All authors have declared no support from any organization for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous 3 years; any other relationships or activities that could appear to have influenced the submitted work.

All authors were involved in the design of the study. PP, MLF, and CM wrote the first draft. All authors have approved the final version of the manuscript submitted for publication.

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https://doi.org/10.1016/j.spinee.2018.05.018
1529-9430/

Introduction

Low back pain (LBP) is a highly prevalent condition, and it is associated with significant disability and work absenteeism worldwide [1]. Not surprisingly, the costs associated with LBP are enormous, causing major economic burden for patients, government, and health insurance companies [2,3]. A better understanding of the risks factors for an episode of LBP may provide important insights into the prevention and management of this condition [2,3].

A variety of environmental and individual characteristics have been reported to increase the risk of LBP [4–9]. These factors can be aggregated into categories including characteristics of the individual (eg, age and gender), physical stress on the spine (eg, regular lifting and whole body vibration), poor general health (eg, smoking and obesity), and psychological stress (eg, monotonous work and depression). Numerous systematic reviews and meta-analyses of risk factors associated with LBP and sciatica have been published [4,5,7,9,10]. However, these previous studies have been criticized as being too narrowly focused on a subset of these risk factors.

To our knowledge, there has been no previous attempt to summarize the evidence from existing systematic reviews of risk factors for LBP or sciatica. Therefore, to provide an overview of risk factors for LBP, we completed an umbrella review of the evidence from existing systematic reviews.

Methods

Data sources and searches

A systematic literature search was conducted in MEDLINE, EMBASE, PubMed PsychINFO, and CINAHL databases, using keywords, MeSH, and other index terms, as well as combinations of these terms and appropriate synonyms. The date of the last search was May 2016. There were no restrictions on language. In addition to the electronic database searches, we conducted citation tracking (checking the reference lists of all included studies) for additional relevant reviews. Detailed search strategies used for each database are described in Appendix S1.

Study selection

To show the most recent evidence, we only included systematic reviews published in the last 5 years (2011–2016) examining any risk factor for LBP and sciatica. Only systematic reviews that included cohort studies enrolling participants who were free of LBP and sciatica at baseline were included. Cross-sectional design, editorial or narrative review, methodological studies, and studies with small sample size were excluded. For a review to be considered systematic, the authors must have defined a strategy to (1) search for studies, (2) appraise studies, and (3) synthesize studies. Selection of reviews was conducted in three steps: (1) by screening the title, (2) by reading the abstracts, and (3) by reading the full text. Two independent reviewers (PP and DS) performed the selection of the systematic reviews and resolved differences by consensus. A third review author arbitrated if disagreements persisted (CM). Excluded were editorials, correspondence, abstracts, and summaries of reviews.

Data extraction

Data extraction was performed by two independent reviewers (PP and DS) using a standardized data extraction form and in the case of disagreements, consensus was obtained through discussion or arbitration by a third reviewer (CGM), if required. The characteristics of all systematic reviews were summarized descriptively. From each eligible review, we recorded the first author name, year of publication, risk factors examined, outcomes, measures of risk (eg, odds ratio or hazard ratio) and 95% confidence intervals, number of studies included, and main conclusions.

Data synthesis

Evidence tables were produced to show the results and methodological quality for each systematic review grouped by risk factor.

Methodological quality assessment

The methodological quality of the included systematic reviews was assessed by two independent reviewers (PP and DS) using the Assessment of Multiple Systematic Reviews (AMSTAR) tool [11]. AMSTAR is a validated instrument that uses 11 questions to assess the degree to which review methods are unbiased. Any disagreements were resolved by discussion. Consistent with other AMSTAR-based assessments [12,13], we collapsed AMSTAR scores into three categories: "high" (≥8 of 11 points), "moderate" (4–7 points), and "low" (≤3 points). The AMSTAR instrument can be found in Appendix S3.

Reliability assessments

The reliability assessments were performed for study selection, data extraction, and quality assessment.

Results

Study selection and data extraction

The study selection and data extraction was performed by two independent reviewers. Reviewers disagreed once during the selection of the studies and three times during the data extraction. All disagreements were resolved by third reviewer arbitration. From the electronic search, 629 potentially relevant articles were retrieved. Of these, 15 systematic reviews were considered eligible and were included (Figure).

Description of studies

Systematic reviews evaluated 36 risk factors associated with increased risk of LBP and 14 risk factors associated with

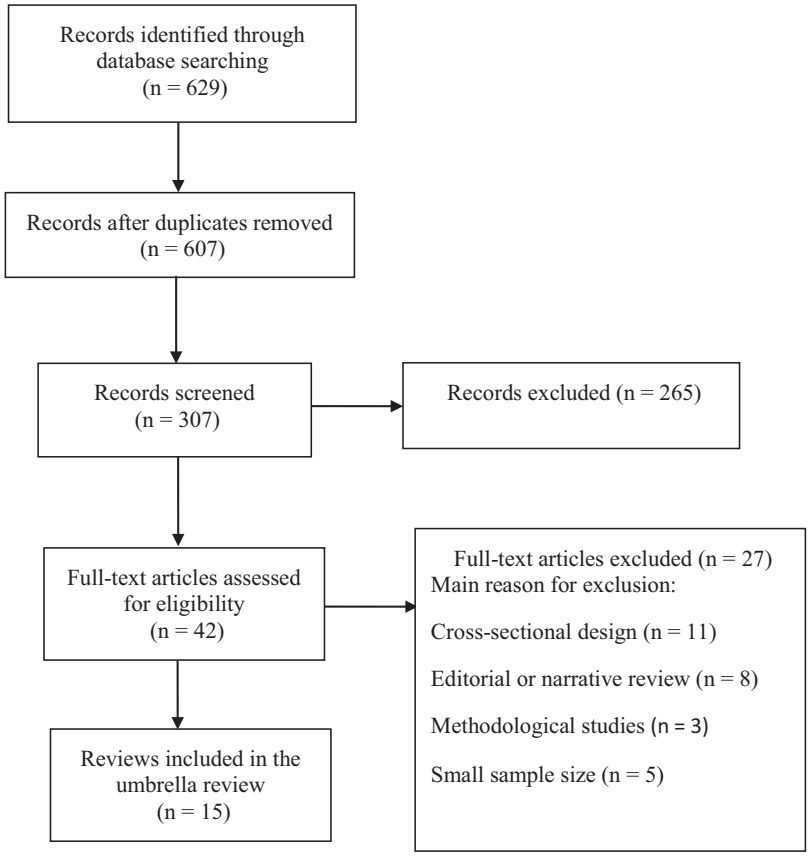

Figure. Flow chart of literature search for systematic reviews and meta-analyses.

increased risk of sciatica. The median number of cohort studies included in the systematic reviews was four (range 1–40). Only three [6,9,14] systematic reviews performed meta-analyses of their results.

Of the studies included in the reviews, follow-up periods ranged from 1 to 12 years. Low back pain outcome measures used also varied between reviews and included questionnaires and physical tests. A description of risk factor categories and overall results of included studies is presented in Tables 1 and 2. When the same review presented odds ratios from different studies for the same risk factor, we reported the range (ie, the lowest and highest value of odds ratio were reported). If the review pooled odds ratios we presented the pooled estimate. In cases when there were multiple reviews for a risk factor, we selected data from the most recent or highest quality systematic review. Detailed data extraction can be found in Appendix S2. Table 3 describes the LBP outcomes (ie, episode of LBP with care seeking, episode of LBP causing work absence) for all included systematic reviews.

The methodological quality of the included reviews is shown in Table 4. The total AMSTAR score ranged from 4 to 9 points (on a scale ranging from 0 to 11 points, mean score of 6.20 points; SD=1.30). Questions most frequently satisfied were question 4 (related to inclusion criteria) and question 7 (related to quality of the included studies). Questions less frequently satisfied were question 1 (related to the study question and inclusion criteria) and question 5 (related to inclusion and exclusion list of studies).

An evaluation of inter-rater reliability was performed for study selection, data extraction, and quality assessment. For study selection, kappa coefficient was 0.84; for quality assessment (AMSTAR tool), the intraclass correlation coefficient was 0.93 (95% confidence interval [CI]=0.80–0.99), showing a high level of reliability. Also, the reliability was assessed for each question of AMSTAR tool. For question 2 (duplicate study selection and data extraction), question 4 (inclusion of gray literature), question 8 (scientific quality of included studies used appropriately in formulating conclusion), question 9 (appropriateness of methods used to combine studies' findings), and question 11 (conflict of interest), the kappa coefficient was 1.0. For question 5 (included and excluded studies provided) and question 6 (characteristics of the included studies provided), the kappa coefficient was 0.71. Question 1 (a priori design) and question 10 (likelihood of publication bias) had the lowest kappa coefficient (0.44 and 0.23, respectively)

Discussion

Statement of principal findings

This umbrella review provides an overview of risk factors evaluated for their association with LBP and sciatica.

Table 1
Risk factors for low back pain investigated in included systematic reviews (n=13)*

	Risk factor	Odds ratio (95% CI)	AMSTAR	Number of cohort studies/ number of participants
Individual	Age (18–44 y versus 44–75 y)†	2.8 (1.3–5.9) [15]	7	OR from one study/N=468
	Male gender	Unclear [15]	7	OR from two studies/N=1,633
	Previous low back pain (yes/no)	Ranged from 1.71 (1.32–2.20) to 6.1 (4.1–9.1) [15]	7	OR from four studies/N=4,538
	Height (>170 cm)	1.7 (1.0–2.6) [15]	7	OR from one study/N=1,366
	Puberty (adolescents >19 y)	1.5 (1.2–1.8) [8]	7	OR from one study/N=4,226
Poor general health	Smoking (current smokers)	1.88 (1.3–2.7) [16]	6	OR from one study/N=1,960
	Obesity (BMI<24)	1.43 (0.9–1.0) [7]	8	OR from one study/N=963
	Alcohol (>1 unit/day)	0.9 (0.6–1.2) [17]	5	OR from one study/N=5,349
	Physical activity§	Unclear [10]	5	OR from five studies/N=54,125
	Chronic diseases (“having chronic disease”) (yes/no)	1.7 (1.2–2.4) [15]	7	OR from one study/N=2,256
	Sleep problems§	3.2 (1.9–5.5) [15]	7	OR from one study/N=2,256
	Frequently feeling tired§	1.8 (1.4–2.3) [15]	7	OR from one study/N=1,366
	Pain at any other regional site (yes/no)	1.7 (1.2–2.4) [15]	7	OR from one study/N=625
Physical stress	Whole-body vibration*,‡	2.1 (1.6–2.9) [4]	7	OR from one study/N=1,108
	Lifting >25 kg‡	1.1 (1.05–1.1) [6]	8	Pooled OR from six studies/N=21,919
	Lifting (frequency)‡	1.09 (1.03–1.15)† [6]	8	Pooled OR from three studies/N=15,514
	Sitting >2 h	0.4 (0.2–0.7) [15]	7	OR from one study/N=709
	Time driving (for >2 h)	4.8 (1.4–16.4) [15]	7	OR from one study/N=501
	Pulling >56 lb	2.1 (1.2–3.4) [15]	7	OR from one study/N=625
	Kneeling >15 min	2.1 (1.3–3.3) [15]	7	OR from one study/N=625
	Squatting >15 min	1.8 (1.1–3.1) [15]	7	OR from one study/N=625
	Bending forward and backward (often)§	Ranged from 1.6 (1.1–2.3) to 2.20 (1.4–3.4) [15]	7	OR from two studies/N=1,466
	Working with hands above shoulders (0–15 min)	1.6 (1.1–2.4) [15]	7	OR from one study/N=625
	Flexed posture (>60 trunk flexion for >5% of the time)	1.47 (1.0–2.1) [15]	7	OR from one study/N=861
	Prolonged standing or walking (>2 h)	2.9 (1.5–5.5) [15]	7	OR from one study/N=468
	Physical activity (specific occupational loads)§	Ranged from 1.6 (1.1–2.4) to 5.7 (3.7–8.8) [15]	7	OR from six studies/N=33,660
	Current military active duty (yes/no)	1.44 (1.1–1.9) [15]	7	OR from one study/N=1,230
Psychological stress	Employment social support (coworker)§	Unclear [18]	7	OR from six studies/N=9,187
	Employment social support (supervisor)§	Unclear [18]	7	OR from six studies/N=9,637
	Employment social support (general work)§	Unclear [18]	7	OR from 10 studies/N=6,942
	Monotonous work (yes/no)	2.3 (1.1–5.1) [15]	7	OR from one study/N=836
	Mental distress—being stressed, nervous, or tense (yes/no)	2.2 (1.3–3.7) [15]	7	OR from one study/N=2,256
	Dissatisfaction with life (yes/no)	1.8 (1.2–2.6) [15]	7	OR from one study/N=2,256
	Depression‡(yes/no)	1.6 (1.3–2.0)† [9]		Pooled OR from 11 studies/N=23,109
	Psychosomatic factors§	2.5 (1.2–5.1) [15]	7	OR from one study/N=2,256
Other	Comfort of car seat§	1.9 (1.0–3.7) [15]	7	OR from one study/N=601

BMI, body mass index; kg, kilogram; lb, pounds; AMSTAR, Assessment of Multiple Systematic Reviews; CI, confidence interval; OR, odds ratio.
* Results from the most recent or highest quality systematic reviews.
† For females only.
‡ Data from meta-analyses.
§ Definition not provided in paper.

Overall, included systematic reviews varied from moderate to high methodological quality. Our results showed that exposure to a range of factors pertaining to the individual, poor general health, physical stress, and psychological stress significantly increased the risk of LBP and sciatica. Of the 54 risk factors investigated, this review identified a number of risk factors that are likely to be modifiable and therefore potential targets for prevention interventions. Examples include sleep problems (severe) (OR=3.2, 95% CI=1.9–5.5), time driving (OR=4.8, 95% CI=1.4–16.4), and prolonged standing or walking (OR=2.9, 95% CI=1.5–5.5).

Strengths and weaknesses of the study

To our knowledge, this is the first umbrella review investigating risk factors for the onset of both LBP and sciatica. To comply with current guidelines on the conduct of high-quality reviews, we registered the protocol, included a comprehensive search strategy, assessed the quality of included

Table 2
Risk factors for sciatica investigated in included systematic reviews (n=2)*

	Risk factor	Odds ratio (95% CI)	AMSTAR	Number of cohort studies/ number of participants
Individual	Previous low back pain (yes/no)	Ranged from 1.5 (1.2–1.9) to 4.5 (2.7–7.6) [19]	7	OR from three studies/N=7,251
	Age (>60 y)	Ranged from 2.5 (1.4–4.2) to 3.5 (1.9–6.5) [19]	7	OR from two studies/N=59,077
	Height (>180 cm)	2.7 (1.2–6.3) [19]	7	OR from one study/N=841
Poor general health	Obesity† (>normal weight)	1.7 (1.1–2.4) [14]	4	OR from four studies/N=1,553
	Smoking (current smoker)	Ranged from 1.5 (1.1–2.1) to 9.6 (1.7–53.0) [19]	7	OR from three studies/N=7,701
Physical stress	Drive for >2 h >once/wk	2.7 (1.2–6.4) [19]	7	OR from one study/N=841
	Manual laborer (>2 h/d)	1.5 (1.1–2.1) [19]	7	OR from one study/N=5,261
	Routine laborer (>2 h/d)	1.2 (1.0–1.4) [19]	7	OR from one study/N=5,261
	Moderate twisting of the trunk‡	1.7 (1.2–2.4) [19]	7	OR from one study/N=2,077
	Working with the trunk forward flexed (>2 h/d)	2.1 (1.4–3.2) [19]	7	OR from one study/N=2,077
	Moderate walking‡	1.3 (1.0–1.6) [19]	7	OR from one study/N=1,149
	Active walking (moderate walking)‡	2.2 (1.5–3.4) [19]	7	OR from one study/N=2,077

AMSTAR, Assessment of Multiple Systematic Reviews; CI, confidence interval; OR, odds ratio.
* Results from the most recent or highest quality systematic reviews.
† Data from meta-analyses.
‡ Definition not provided in paper.

studies, and used strict inclusion criteria. As we aimed to assess a possible pathway between risk factors and LBP and sciatica, we only included cohort studies that enrolled participants free of LBP at baseline.

This review has some limitations that should be considered. Most risk factors were tested in single studies, and in cases when there were multiple studies, there was often insufficient data in the reviews to allow pooling. Another limitation was the heterogeneity in the definition of a future episode of LBP, and the classification of being free of LBP and sciatica at study entry. Some of the included reviews investigated a future episode of LBP in a population without a previous history of the condition, whereas other studies investigated a future episode of LBP among people who had reported LBP before (recurrence). Most of the definitions for a recurrent episode of LBP in the included studies match the consensus definition, in which a future case of LBP is defined as an episode lasting at least 24 hours [23].

Table 3
Number of cohort studies per review and outcomes

Author, year	LBP	Work absence	Seeking care	Disability
Burstrom et al., 2015	4	0	0	0
Campbell et al., 2013	17	0	0	3
Coenen et al., 2014	6	0	0	0
Cook et al., 2014	8	0	0	0
Dario et al., 2015	1	0	0	0
Ferreira et al., 2013a	3	0	0	0
Ferreira et al., 2013b	1	0	0	0
Heneweer et al., 2011	21	7	4	2
Janwantanakul et al., 2012 [20]	3	0	0	0
Lardon et al., 2014	2	0	0	0
Pinheiro et al., 2015	11	0	3	1
Ribeiro et al., 2012 [21]	5	0	0	0
Shiri et al., 2014	9	0	0	0
Sitthipornvorakul et al., 2011 [22]	2	0	0	0
Taylor et al., 2014	41	0	0	0

LBP, low back pain.

Possible explanations and mechanisms

Our study identified that poor general health and individual, psychological, and physical risk factors were associated with LBP and sciatica. There are some possible explanations for the association between some of these risk factors and LBP and sciatica. Regarding poor general health, sleep problems were found to increase the risk of future LBP. Recent research suggests that sleep quality and pain intensity are intimately linked. Experimental studies in healthy volunteers (without pain) have demonstrated that induced sleep deprivation, via either a reduction in sleep duration or disruption of sleep architecture, leads to the development of musculoskeletal pain and increased pain sensitivity to noxious stimuli [24,25]. With regard to physical stress, the effect of lifting on LBP can potentially be explained by the high mechanical loads (spinal compression forces) on the low back during lifting. Finally, psychological stress represents an important and complex risk factor for related LBP disorders. A common theory holds that depression and painful symptoms follow the same descending pathways of the central nervous system [26,27]. However, a complete picture of this relationship would be much more complex, acknowledging the moderating role of individual and contextual factors, such as personality traits, cognitive styles, physiological mechanisms, or social support, among others.

Implications for clinicians or policymakers

A better understanding of risk factors for LBP provides a logical rationale, which is currently lacking, for the devel-

Table 4
Methodological quality of the included systematic reviews based on AMSTAR criteria and scores*

Author, year	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Total
Burstrom et al., 2015	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	8
Campbell et al., 2013	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	Yes	7
Coenen et al., 2014	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	8
Cook et al., 2014	No	No	No	Yes	No	Yes	Yes	No	No	No	Yes	4
Dario et al., 2015	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	8
Ferreira et al., 2013a	No	No	Yes	Yes	No	No	Yes	Yes	Yes	No	No	5
Ferreira et al., 2013b	No	No	Yes	Yes	No	No	Yes	Yes	Yes	No	Yes	6
Heneweer et al., 2011	No	Yes	Yes	Yes	No	No	Yes	Yes	No	No	No	5
Janwantanakul et al., 2012 [20]	No	No	Yes	Yes	No	No	Yes	Yes	No	No	Yes	5
Lardon et al., 2014	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	N/A	No	7
Pinheiro et al., 2015	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	9
Ribeiro et al., 2012 [21]	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	Yes	7
Shiri et al., 2014	No	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	7
Sitthipornvorakul et al., 2011 [22]	No	No	Yes	Yes	No	No	Yes	Yes	No	No	Yes	5
Taylor et al., 2014	No	No	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	7

AMSTAR, Assessment of Multiple Systematic Reviews; N/A, not available.

* Q1: A priori design; Q2: Duplicate study selection and data extraction; Q3: Search comprehensiveness; Q4: Inclusion of gray literature; Q5: Included and excluded studies provided; Q6: Characteristics of the included studies provided; Q7: Scientific quality of the primary studies assessed and documented; Q8: Scientific quality of included studies used appropriately in formulating conclusions; Q9: Appropriateness of methods used to combine studies' findings; Q10: Likelihood of publication bias was assessed; Q11: Conflict of interest—potential sources of support were clearly acknowledged in both the systematic review and the included studies.

opment of more effective prevention strategies. Our results found a number of risk factors significantly associated with developing LBP. However, some of them are largely under-recognized by clinicians and policymakers. A better understanding of these under-recognized risk factors provides a logical rationale for the development of more effective prevention strategies. For instance, this review identified some risk factors that are likely to be modifiable and therefore potential targets for prevention interventions. Clinicians could use this information to advise patients about potential risk factors to avoid and to reduce the risk of developing LBP. Monitoring exposure to these risk factors could help avoid cases of LBP.

Conclusions

This umbrella review provides evidence that poor general health, physical and psychological stress, and characteristics of the person increase the risk for a future episode of LBP and sciatica. These results aid our understanding of the potential triggers of LBP and sciatica, providing valuable information to the development of new prevention strategies for this troublesome condition.

Supplementary material

Supplementary material related to this article can be found at https://doi.org/10.1016/j.spinee.10.1016/j.spinee.2018.05.018.

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Chapter Three

Can patients identify what triggers their back pain? Secondary analysis of a case-crossover study

Chapter Three has been presented as:

Parreira P.; Maher CG; Latimer J.; Steffens D.; Blyth F.; Li Q.; Ferreira ML. *Can patients identify what triggers their back pain? Secondary analysis of a case-crossover*. Pain. 2015 Oct; 156 (10):1913-9. Reprinted with permission from Wolters Kluwer.

Statement from co-authors confirming authorship contribution of the PhD Candidate

The co-authors of the paper: *"Parreira P.; Maher CG; Latimer J.; Steffens D.; Blyth F.; Li Q.; Ferreira ML. Can patients identify what triggers their back pain? Secondary analysis of a case-crossover. Pain. 2015 Oct; 156 (10):1913-9"*confirm that Patricia C S Parreira has made the primary contribution to this study in each of the following areas:

• Conception and design of the research

• Interpretation of findings

• Writing of the manuscript and critical appraisal of content

In addition to the statements above, in cases where I am not the corresponding author of a published item, permission to include the published material has been granted by the corresponding author.

Patricia do Carmo Silva Parreira _____08/07/2018

As supervisor for the candidature upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

Professor Chris Maher_____ 08/07/2018

Research Paper

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Can patients identify what triggers their back pain? Secondary analysis of a case-crossover study

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Abstract

The aim of this case-crossover study was to investigate the extent to which patients can accurately nominate what triggered their new episode of sudden-onset acute low back pain (LBP). We interviewed 999 primary care patients to record exposure to 12 standard triggers and also asked the patients to nominate what they believed triggered their LBP. Exposure to the patient-nominated trigger during the case window was compared with exposure in the control window. Conditional logistic regression models were constructed to quantify the risk of LBP onset associated with the patient-nominated trigger. Sensitivity analyses were conducted varying the duration and timing of case/control windows. We compared the extent to which patient-nominated triggers matched standard triggers. The odds ratios for exposure to patient-nominated triggers ranged from 8.60 to 30.00, suggesting that exposure increases the risk of LBP. Patients' understanding of triggers however seems incomplete, as we found evidence that while some of the standard triggers were well recognised (such as lifting heavy loads), others (such as being distracted during manual tasks) were under-recognised as possible triggers of an episode of LBP. This study provides some evidence that patients can accurately nominate the activity that triggered their new episode of sudden-onset acute LBP.

Keywords: Low back pain, Risk factors, Observational

1. Introduction

Low back pain (LBP) is the leading cause of activity limitation and work absence throughout much of the world.[9] As reported in the Global Burden of Disease Study 2010 (GBD 2010), LBP is 1 of the 10 leading causes of years lived with disability.[25] Along with the high prevalence and burden on individuals, the costs associated with LBP are very large.[3] Globally, costs due to work productivity losses along with health care expenditure are responsible for the bulk of the societal cost of LBP.[3] Despite the high prevalence and costs, there is limited knowledge of what triggers an episode of LBP.

Low back pain is a complex condition; many risk factors are believed to contribute to its onset.[12] A range of biomechanical, psychological/psychosocial, and individual characteristics has been identified as risk factors for LBP.[6,11,15] Some risk factors such as being overweight involve prolonged exposure, whereas triggers such as lifting awkwardly involve short-term transient exposure just before the onset of LBP. Understanding factors that trigger an episode of LBP may provide important insights into the prevention and management of this condition.[23,24]

Patients' views represent an important field of health care research.[18] Until now, research into patients' views regarding factors that trigger an episode of LBP has been conducted using qualitative methods.[5,13,18,20] In these studies, participants displayed biomedical beliefs about triggers of LBP, typically attributing pain to structural/anatomical vulnerability of the spine and exposure to heavy manual tasks. However, these results are based on qualitative studies examining expectations and beliefs about the causes of LBP. To our knowledge, no study has used a quantitative paradigm to evaluate whether patients can accurately identify what triggered their episode of LBP. Should it be demonstrated that patients can accurately identify these triggers then clinicians could apply this information when developing individual treatment and prevention programmes.

The aim of this study was to investigate the extent to which patients can accurately nominate what has triggered their new episode of sudden-onset acute LBP. We hypothesised that in general, patients would be able to identify the trigger for their LBP but that there may be some types of triggers that are missed (ie, under-recognised) and others that are over-recognised.

2. Methods

2.1. Study design

Data for this study were obtained from the TRIGGERS for LBP study.[22,23] TRIGGERS is a case-crossover study that investigated the increase in risk of a sudden episode of LBP associated with transient exposure to 12 standard triggers (eg, heavy loads, awkward posture, objects not close to the body, live people or animals, unstable/unbalanced/difficult to grasp or hold loads, vigorous physical activity, moderate physical activity, slip/trip/fall,

Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

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PAIN 156 (2015) 1913–1919

http://dx.doi.org/10.1097/j.pain.0000000000000252

sexual activity, consumption of alcohol, distracted during an activity or task, and fatigued/tired). The increase in risk was assessed by comparing exposure to these standard triggers immediately before pain onset with exposure 24 hours before pain onset in people presenting to primary care with an acute episode of back pain. The 12 standard triggers were obtained from the list of hazardous tasks provided in the National Code of Practice.[19] Additionally, a number of factors that had been previously identified as triggers in occupational injury studies, but never evaluated in the area of back pain, were included. Exposure information was collected during a phone interview for each participant. After collecting information on exposure to the 12 standard triggers, each patient was asked to nominate, using free text, what they believed was the trigger for their episode of LBP (ie, patient-nominated trigger).

We evaluated the accuracy of the patient-nominated triggers in 3 ways. First, we quantified the risk of developing a new episode of LBP associated with exposure to the patient-nominated triggers without distinguishing between the various types of triggers nominated. This tested the hypothesis that if patients could accurately identify the trigger for their LBP, we would expect to see a positive measure of association (high odds ratio [OR]) for the patient-nominated trigger. Second, we repeated this analysis but only including the subset of participants for whom the nominated trigger was 1 of the 12 standard triggers. Third, we compared the distribution of exposure to patient-nominated triggers with the distribution of exposure to the corresponding standard triggers. At the group level, we expected patients to nominate more frequently the standard triggers we had previously shown to be strongly associated with episodes of LBP and nominate less frequently the triggers with a weaker or no association (OR close to 1). The third analysis allowed us to estimate whether patients underestimate or overestimate the harmful effects of certain triggers.

2.2. Participants

Consecutive patients with a new episode of acute LBP, aged 18 years or older, of either gender, were recruited. The study recruited from primary care clinics in New South Wales, Australia, between October 2011 and November 2012. A new episode of LBP was defined as a primary complaint of pain between the 12th rib and the buttock crease, with or without leg pain, causing the patient to seek health care or take medication, and preceded by a period of at least 1 month without pain.[4] Patients presenting with first-ever episodes or recurrent episodes were eligible as long as they fitted the definition of a new episode of LBP. To be eligible to enter the study, participants had to meet all of the following criteria: (1) comprehend spoken English, (2) primary complaint of pain in the area between the 12th rib and the buttock crease, with or without leg pain, (3) pain of least moderate intensity during the first 24 hours of the episode (assessed using a modified version of item 7 of the SF-36), (4) presentation for treatment within 7 days from the time of pain onset. Patients with metastatic, inflammatory, or infectious disease of the spine, cauda equina syndrome, and spinal fracture were excluded from the study.[10] All participants gave written informed consent for participation. Ethical approval for the study was granted by The University of Sydney Human Research Ethics Committee (protocol number 05-2011/13742).

2.3. Study interview

Trained research staff used an interview script to collect socio-demographic and clinical characteristics from the participant as well as data on exposure to a variety of possible triggers. During the interview, participants were asked to identify the date and time of pain onset. The interview script was piloted on 20 subjects with back pain and adjustments made to improve clarity and participant recall. Design features were included to minimise recall bias. For instance, to be eligible, participants had to present within 7 days of the onset of back pain, as this short time between the event and reporting of the event would facilitate recall of activities. In addition, trained research staff asked participants to use prompts such as referring to their agenda, calendar, and/or smartphones to enhance their memory of the activities they performed in the days before the onset of their LBP.

Assisted by research staff, participants were then asked to report exposure to each of the 12 standard triggers, including time of occurrence and duration, over the 96 hours preceding the onset of LBP. The time period of 96 hours was used so that participants, clinicians, and interviewers would remain blinded to the case and control windows. This was done to reduce any differential misreporting by patients or interviewers to fit case and control windows. The time and duration of exposure for each standard trigger was recorded.

In the final portion of the interview, participants were asked to nominate what they thought might have triggered their LBP (ie, patient-nominated trigger) with the following question: "What do you think may have triggered your LBP?" The exposure to the patient-nominated trigger was recorded, and it was noted whether this occurred on the day of LBP, the day before, 2 days before, or 3 days before.

2.4. Data coding

The patient-nominated triggers were then matched to the 12 standard triggers and coded by 2 independent researchers. A patient-nominated trigger could match none, 1, or more of the 12 standard triggers. Any discrepancies were resolved by discussion and consensus. If consensus could not be obtained, a third researcher made the final decision.

The purpose of matching the patient-nominated triggers to the standard triggers was to allow for a more precise determination of the duration of exposure to a patient-nominated trigger. This was because in the original TRIGGERS study,[23] exposure to standard triggers was recorded in 10-minute time epochs, whereas exposure to patient-nominated triggers was only recorded in days.

2.5. Statistical analysis

Conditional logistic regression models were constructed to quantify the risk of LBP onset associated with each patient-nominated trigger, where each participant represented a matched set of data for case and control exposures. The time periods of occurrence and duration of exposure were similar for the original TRIGGERS study and the current study. In the original TRIGGERS study, the frequency of exposure to each trigger was calculated for the case (2 hours before the onset of back pain) and 2 control windows (24-26 hours and 48-50 hours before the onset of back pain, respectively). In the current study, we performed 2 analyses. First, we built a model comparing exposure to the patient-nominated trigger on the day of the event (case window) with exposure 2 days before the event (control window). Sensitivity analyses were also conducted with the control window being 3 days before the event. Windows of 24-hour duration were used in this analysis, as we did not know the precise time of day the participant was exposed to the patient-nominated trigger. By selecting the control window 2 days before, we ensured that there

was at least 24 hours between exposures in the case and control windows. We did not select a control window 1 day before because exposure at the end of this control window and exposure at the beginning of the case window would not be separated by a full 24 hours (theoretically, they may be separated by less than a minute). Risk of an episode of sudden acute LBP was expressed using ORs and 95% confidence intervals (CIs).

A second analysis was conducted on the subset of participants for whom the patient-nominated trigger matched 1 of the 12 standard triggers. This allowed for more precise estimation of exposure period, in 10-minute time epochs, and therefore the analysis included 2-hour case windows immediately preceding the LBP onset and 2-hour control windows occurring 24 hours before the onset of LBP (eg, 24-26 hours). This subgroup analysis was only performed where there was sufficient endorsement for a trigger (ie, minimum number of 50 participants per analysis).

To evaluate whether patients underestimate or overestimate the harmful effects of certain triggers, the distribution of exposure to patient-nominated triggers was compared with the distribution of exposure to the corresponding standard triggers previously reported in the original TRIGGERS study.[23]

3. Results

Of the 999 participants included in the original TRIGGERS study,[23] a total of 679 (67.9%) patients nominated an activity as responsible for their episode of LBP. Analyses were made only with patients who identified 1 or more of the 12 standard triggers (**Fig. 1**). The characteristics of the participants who nominated an activity are presented in **Table 1**. Just over half the sample were male (58.6%), with a mean (SD) age of 44 years (13.8). In the first 24 hours after pain onset, the majority of participants rated the pain as severe (50.1%) and the mean (SD) duration of the current episode was 4.8 (2.7) days. Patients typically presented to health care a mean (SD) of 3.0 (2.1) days from the pain onset.

The frequency of exposure to patient-nominated triggers on the day of the LBP onset (case window) and 2 days (first control window) or 3 days (second control windows) preceding the pain episode with the associated ORs are presented in **Table 2**. For all analyses, exposure to the patient-nominated trigger increased the odds of developing an acute episode of LBP. For the primary analysis, the OR (95% CI) was 8.60 (6.68-11.07), and for the secondary analyses, the OR (95% CI) was 11.96 (8.94-16.01).

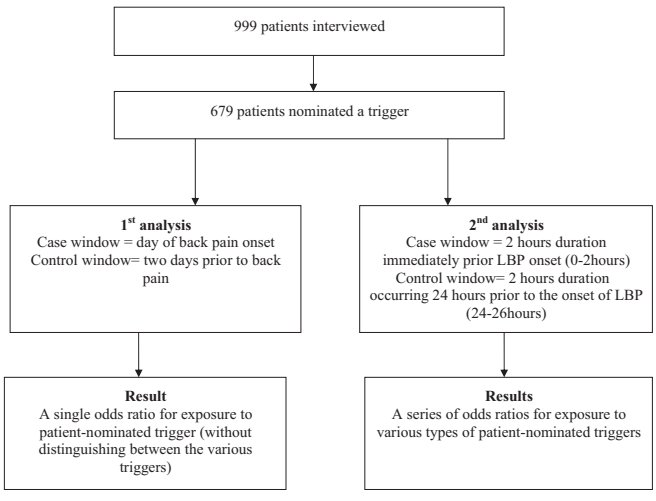

Figure 1. Study flowchart.

The results of the second analysis, using a more precise timing of exposure to a patient-nominated trigger, are shown in **Table 3**. Exposure frequencies were too small for some triggers to be sensibly included in the regression analyses. For all 5 triggers included in the regression analysis, participants were more likely to be exposed to the patient-nominated trigger in the case window (ie, first 24 hours preceding pain onset) than in the control window. For example, in many cases, patients nominated triggers, which had been previously found in the original TRIGGERS study[23] to be associated with large ORs (eg, heavy lifting), suggesting that patients' perceptions are well aligned with the evidence. However, there were a few triggers for which we found evidence of an increased risk in the main study, but were rarely endorsed by patients as a trigger in our study. For instance, being distracted during a manual task and manual tasks involving an object not close to the body were infrequently nominated by

Table 1

Characteristics of the participants (n = 679).

Characteristics	Participants
Age, mean (SD), y	44.7 (13.8)
Male sex, n (%)	398 (58.6)
Height, mean (SD), cm	172.9 (10.4)
Weight, mean (SD), kg	79.5 (18.1)
Body mass index, mean (SD), kg/m^2	26.4 (5.2)
Duration of current episode, mean (SD), d	4.8 (2.7)
Number of previous episodes, mean (SD)	5.9 (14.7)
Days to seek care, mean (SD)	3.0 (2.1)
Days from presentation to health care and interview, mean (SD)	1.9 (2.0)
Days of reduced activity, mean (SD)	2.3 (2.1)
Pain scores (0-10), mean (SD)	5.3 (2.1)
Currently taking medication, n (%)	314 (46.2)
Workers' compensation, n (%)	44 (7.3)
If in paid employment, what do you do for a living, n (%)	
Not employed	115 (16.9)
Clerical and administrative worker	69 (10.2)
Community and personal service worker	33 (4.9)
Labourer	23 (3.4)
Machinery operator and driver	25 (3.7)
Manager	106 (15.6)
Professional	220 (32.4)
Sales worker	27 (4.0)
Technician and trade worker	61 (9.0)
Pain location, n (%)	
Upper back	39 (5.7)
Lower back	679 (100)
Left thigh (back)	65 (9.6)
Left leg (back)	23 (3.4)
Right thigh (back)	73 (10.8)
Right leg (back)	32 (4.7)
Right thigh (front)	22 (3.2)
Right leg (front)	6 (0.9)
Left thigh (front)	25 (3.7)
Left leg (front)	7 (1.0)
Pain severity in the first 24 h, n (%)	
Moderate	232 (34.2)
Severe	340 (50.1)
Very severe	107 (15.8)
Pain interfering with work in the first 24 h, n (%)	
Not at all	14 (2.1)
A little bit	65 (9.5)
Moderately	159 (23.4)
Quite a bit	254 (37.4)
Extremely	187 (27.5)

Body mass index: weight in kilograms divided by the square of the height in metres.

Table 2

Exposure frequency and ORs for exposure to patient-nominated triggers (case window vs control window): primary analysis and sensitivity analyses (n = 679).

Case window (0-24 h), n (%)	First control window (0-24 h), n (%)	OR (95% CI)	*P*
Main analysis			
679 (68.0)	170 (17.0)	8.60 (6.68-11.07)	<0.0001
Sensitivity analysis			
679 (68.0)	142 (14.2)	11.96 (8.94-16.01)	<0.0001

CI, confidence interval OR, odds ratio.

patients as the cause of the back pain; however, in the original TRIGGERS study,[22] exposure to these triggers was shown to significantly increase the risk of LBP and patients were frequently exposed to these triggers. The ORs ranged from 9.00 to 30.00, providing evidence suggesting that exposure to these patient-nominated triggers was indeed harmful.

In **Table 4**, columns 2 to 4 show the exposure frequencies and ORs for the 12 standard triggers (as previously reported in Ref. 23) based on the full sample of 999 participants. Column 5 shows the proportion who nominated the standard trigger as the cause of their LBP. It can be seen that patients frequently nominated some of the triggers with high ORs (eg, heavy loads, awkward postures) and infrequently nominated some of the triggers with ORs close to 1 (eg, consumption of alcohol). This distribution of responses suggests that they appropriately recognised risk when nominating (or not nominating) this set of triggers. In contrast, for some other triggers (eg, being fatigued or tired), the results suggest that patients may underestimate the risk associated with that trigger (analogous to a false-negative result in a diagnostic study).

4. Discussion

4.1. Statement of principal findings

This study provides evidence that patients can accurately nominate an activity that triggered their sudden-onset acute LBP. The OR for association between patient nominated triggers and risk of developing acute LBP was 8.60 in the primary analysis and 11.96 in the sensitivity analysis, suggesting that patients can identify risk behaviours well. When we repeated the analyses and focussed on specific types of triggers, and used a more precise time window, the ORs ranged from 9.00 to 30.00, again suggesting that patients had in fact identified substantially risky triggers for a new episode of LBP. However, patients' understanding of triggers seems incomplete, as we also found evidence that certain types of triggers were under-recognised as increasing the risk of an episode of LBP. Triggers such as being distracted during a manual task and manual tasks involving an object not close to the body were infrequently nominated as the cause of the LBP; however, in the original TRIGGERS[22] study,[23] these triggers had high ORs significantly increasing the risk of LBP and patients were frequently exposed to these triggers. This pattern of responses suggests that the risk associated with exposure to these specific triggers is not widely appreciated by patients. There were no examples of triggers with ORs close to 1 that were frequently nominated (ie, a false positive), but there was limited potential for us to identify false positives, as only 2 of the 12 standard triggers had ORs close to 1 in the original study.

4.2. Strengths and weaknesses of the study

A strength of the study was that we enrolled a large representative sample of patients seeking primary care for an acute episode of LBP. We also used the case-crossover design to provide estimates of the transient increase in risk of LBP associated with exposure to various triggers. Case-crossover studies provide perfect matching of known and unknown confounders between cases and controls. Moreover, as in case-crossover studies, participants are only compared with themselves at 2 different times (ie, case vs control windows); individual differences such as age and past pain experience, which could affect participants' recall of symptoms and activities, would impact the case and control windows to the same extent, not influencing therefore the association between exposure and event. Another strength of this study is the fact that we have minimised the recall period to a maximum of 14 days. This is substantially less than many studies including self-report outcomes in the pain literature, for example, the standard version of the SF-36 has a 1-month recall period. The choice of case and control windows can be

Table 3

Exposure frequency and ORs for nominated trigger: second analysis with more precise timing of exposure* (n = 679).

Triggers	Case window (0-2 h), n (%)	First control window (24-26 h), n (%)	OR (95% CI)	*P*
Manual tasks involving				
Heavy loads	106 (56.7)	21 (11.2)	10.44 (5.27-20.70)	<0.001
Awkward posture	73 (62.4)	14 (12.0)	15.75 (5.73-43.27)	<0.001
Objects not close to the body	4 (100)	1 (25.0)	—	—
Live people/animals	35 (60.3)	13 (22.4)	—	—
Unstable/unbalanced/difficult to grasp or hold	3 (37.5)	0 (0.0)	—	—
Vigorous physical activity	41 (46.6)	6 (6.8)	9.75 (3.48-27.28)	<0.001
Moderate physical activity	42 (30.4)	10 (7.3)	9.00 (3.20-25.29)	<0.001
Slip/trip/fall	30 (75.0)	1 (2.5)	30.00 (4.09-219.98)	0.001
Consumption of alcohol	0 (0.0)	0 (0.0)	—	—
Sexual activity	1 (3.3)	0 (0.0)	—	—
Distracted	0 (0.0)	0 (0.0)	—	—
Fatigued/tired	2 (14.3)	2 (14.3)	—	—

* Analysis was conducted on the subset of participants for whom the patient-nominated trigger matched 1 of the 12 standard triggers.
CI, confidence interval; OR, odds ratio.

Table 4

Comparison of risk data from the original TRIGGERS study and participants' endorsement of a trigger as the cause of their back pain.

Triggers	Case window (0-2 h), n (%)	First control window (24-26 h), n (%)	OR*	Nominated trigger, n (%)
Heavy loads	179 (17.9)	64 (6.4)	4.97	187 (18.7)
Awkward posture	274 (27.4)	70 (7.0)	8.03	117 (11.7)
Objects not close to the body	40 (4.0)	14 (1.4)	6.20	4 (0.4)
Live people/animals	86 (8.6)	62 (6.2)	5.80	58 (5.8)
Unstable/unbalanced/difficult to grasp or hold	52 (5.2)	19 (1.9)	5.13	8 (0.8)
Vigorous physical activity only	105 (10.5)	44 (4.4)	3.90	87 (8.7)
Moderate or vigorous physical activity	225 (22.5)	129 (12.9)	2.70	140 (14.0)
Slip/trip/fall	37 (3.7)	1 (0.1)	—	40 (4.0)
Consumption of alcohol	13 (1.3)	9 (0.9)	1.50	1(0.1)
Sexual activity	8 (0.8)	11 (1.1)	0.73	3 (0.3)
Distracted	30 (3.0)	6 (0.6)	25.00	1 (0.1)
Fatigued/tired	118 (11.8)	69 (6.9)	3.72	14 (1.4)

Data are exposure frequency and ORs for the 12 standard triggers and percentage of sample who nominated that trigger (n = 999).
* Based on case and control windows of 2-h duration.
OR, odds ratio.

interpreted as limitation. However, to minimise this limitation, sensitivity analyses were conducted varying the window durations and obtained very similar ORs. Others studies[1,14,17,22] have used this design to quantify the risk associated with transient exposures and published their findings in prestigious journals, suggesting that the methodology is rigorous and well accepted. Another limitation of the study was that participants were seeking treatment for a new episode of acute LBP, and it is unclear whether similar results would have been observed for people not seeking care for LBP or those with persistent symptoms.

4.3. Strengths and weaknesses in relation to other studies, discussing important differences in results

To our knowledge, this is the first study to test the accuracy of patients' views on triggers of acute LBP. Previous qualitative studies[2,5,13,18,21] have evaluated patients' views of potential triggers for an episode of LBP, but these had never been tested before as potential triggers. In these studies, the majority of the participants attributed pain to damage of the disc or wear and tear of the spine. Only 1 study[20] has considered patients' views on general risk factors for LBP. In this study, pairs of twins discordant for LBP were identified and interviewed about what they believed to be responsible for their own or their twin's LBP status. Twins' responses to the closed questioning showed that the factors more frequently perceived as possible reasons for their differences in LBP status were related to physical loading of the spine, such as performing work with heavy loads. A comparison of our findings with previous research would suggest that patients under-recognise some types of triggers. Our study found that physical triggers, such as manual tasks involving heavy loads and awkward postures, were more frequently endorsed by patients as triggers of LBP than other behavioural and psychological factors. While there is strong research demonstrating that some behavioural and psychological factors increase the risk for LBP,[8,10] the 3 we evaluated (consumption of alcohol, distraction, fatigue) were rarely endorsed by patients in this study. This is in accordance with previous studies that have shown that most patients hold biomechanical views about causes of LBP.[2,13,18] Patients seem to have developed a set of narrative strategies that are intended to reduce the risk of being classed as "psychological" cases. Therefore, they begin by emphasising biomechanical causes for their LBP.[16] Patients also seemed to under-recognise certain risky lifting tasks (eg, of the 40 people who were exposed to the trigger "lifting objects not close to the body" in the case window [ie, immediately before pain onset], only 4 attributed this as a potential trigger for their pain onset). A similar pattern occurred with "feeling fatigued or tired", "being distracted", and engaged in "manual tasks involving unstable/unbalanced/difficult to grasp or hold objects". These results suggest that patients' appreciation of risk factors for LBP is incomplete.

4.4. Interpretation of the study: possible explanations and implications for clinicians and policymakers

Patients' ability to identify triggers for LBP is likely informed by their life experiences including previous experience of LBP, their education and beliefs, and worksite training.[2,5] Understanding patients' views strengthens support for previously identified triggers and highlights other relevant risk factors not previously considered as triggers. Our results also indicate some triggers that seem under-recognised and where greater emphasis may be needed in patient education and training. There may be value in clinicians extending the advice they give to patients on how to reduce exposure to the triggers that the patient recognises but, more importantly, to the triggers that they do not typically recognise. Particular emphasis should be placed on the influence of triggers such as distraction and fatigue and more complex forms of manual handling, which are not widely recognised as risky. We did not find any examples of false-positive beliefs about triggers, which is interesting because persistence of an episode of LBP has been linked to erroneous beliefs about pain and physical activity.[7] However, given that we only considered 12 standard triggers, and only 2 were not shown to increase risk, we acknowledge that we had limited ability to investigate this issue.

4.5. Unanswered questions and future research

As this was a reanalysis of an existing data set, we were only able to consider the 12 standard triggers evaluated in the original TRIGGERS study. Examining a different set of triggers would be an important extension of our research. While our study focussed on identification of triggers for an acute episode of LBP, future studies should investigate triggers for exacerbations (or remissions) of persistent LBP. In our view, the most important direction for future research would be to investigate whether this novel information on triggers can be used to develop effective prevention strategies for LBP.

Conflict of interest statement

The authors have no conflicts of interest to declare.

The TRIGGERS study received funding from Australia's National Health and Medical Research Council (Application ID: APP1003608).

Ethical approval for the study was granted by The University of Sydney Human Research Ethics Committee (protocol number 05-2011/13742).

Data sharing: No additional data available.

All authors affirm that the article is an honest, accurate, and transparent account of the study being reported and that no important aspects of the study have been omitted.

Acknowledgements

All authors were involved in the design of the study. PP and DS prepared and cleaned the data. QL performed the statistical analysis. PP, MLF, DS, and CM wrote the first draft. All authors contributed to further drafts. All authors had full access to the data, specifically, the statistical reports and tables arising from the data, and take responsibility for integrity of the data and accuracy of the data analysis. All authors have approved the final version of the manuscript submitted for publication.

Article history:
Received 5 January 2015
Received in revised form 10 May 2015
Accepted 22 May 2015
Available online 1 June 2015

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Chapter Four

A longitudinal study of the influence of comorbidities and lifestyle factors on low back pain in older men

Chapter Four has been presented as:

Parreira PCS, Maher CG, Ferreira ML, Machado GC, Blyth FM, Naganathan V, Waite LM, Seibel MJ, Handelsman D, Cumming RG. *A longitudinal study of the influence of comorbidities and lifestyle factors on low back pain in older men.* Pain. 2017 Aug; 158 (8):1571-1576. Reprinted with permission from Wolters Kluwer.

Statement from co-authors confirming authorship contribution of the PhD Candidate

The co-authors of the paper: *"Parreira PCS, Maher CG, Ferreira ML, Machado GC, Blyth FM, Naganathan V, Waite LM, Seibel MJ, Handelsman D, Cumming RG. Pain. 2017 Aug; 158 (8):1571-1576"*confirm that Patricia C S Parreira has made the primary contribution to this study in each of the following areas:

• Conception and design of the research

• Interpretation of findings

• Writing of the manuscript and critical appraisal of content

In addition to the statements above, in cases where I am not the corresponding author of a published item, permission to include the published material has been granted by the corresponding author.

Patricia do Carmo Silva Parreira _____ Date: 08/07/2018

As supervisor for the candidature upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

Professor Chris Maher_____ Date: 08/07/2018

Research Paper

PAIN®

A longitudinal study of the influence of comorbidities and lifestyle factors on low back pain in older men

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Abstract

Older adults are largely under-represented in low back pain (LBP) research. In light of the ageing population, it is crucial to understand the influence of comorbidities and lifestyle factors on the risk and prognosis of LBP in older adults. The aims of this study were to describe the course of LBP in older men; to investigate whether comorbidities/lifestyle factors can predict the course of LBP in older men; to assess if comorbidities/lifestyle factors increase the risk of developing LBP in older men. The study sample comprised 1685 older men living in suburban Sydney, Australia. Low back pain, sociodemographic measures, lifestyle factors, and comorbidities were assessed. Of the 1012 men with LBP at baseline, 58% still reported having pain at the 24-month follow-up. Of those without pain at baseline (n = 673), 28% reported pain at follow-up. The odds of persistent pain at 24 months increased with each additional alcoholic drink/wk (odds ratio [OR] = 1.10, 95% confidence interval [CI]: 1.01-1.22; $P = 0.03$) and each additional unit of body mass index (OR = 1.28, 95% CI: 1.04-1.60; $P = 0.02$), but reduced for men who speak English at home (OR = 0.58, 95% CI: 0.35-0.96; $P = 0.03$). In older men, free of LBP at baseline (n = 673), for every additional comorbidity there was an increased risk of developing LBP (OR = 1.17, 95% CI: 1.00-1.37; $P = 0.05$). These results demonstrate the influence of lifestyle factors and comorbidities on LBP in older men and suggest that the consideration of these issues in management may improve outcomes.

Keywords: Low back pain, Older men, Prognosis factors, Risk factors, Observational

1. Background

Low back pain (LBP) is one of the most common musculoskeletal disorders among adults aged 65 years and over.[14] The impact of LBP on older people is significant, for example, it is the most common reason for older Australians to retire involuntarily, with the negative effect on Australia's Gross Domestic Product estimated at $3.2 billion each year.[12] Despite the high prevalence and costs, little is known about risk factors for developing LBP, or the course and prognostic factors for LBP in older adults.

Despite extensive research conducted into LBP, older adults are largely under-represented.[3] As a result, it is likely that clinicians assess and treat older patients based on evidence from studies of the younger population.[18] The degree to which research on young adults is generalisable to older adults is questionable, as there are fundamental differences between these populations including associated comorbidities, lifestyle, and economic factors.[17]

Lifestyle factors and comorbidities both influence health outcomes, such as pain, and are associated with the development or progression of common chronic conditions. For example, some lifestyle behaviours, such as smoking and physical inactivity, are known risk factors for cardiovascular disease and have a worse prognosis for people with diabetes mellitus.[2,9,16] Consideration of comorbidities is more complex because of the interaction between disease states. In general, it is known that the number of health comorbidities rises substantially with age and is associated with an increase in bodily pain and greater limitations in activities of daily living.[4,9] Although the relationship between lifestyle factors and comorbidities has been explored for some disease states,[9] few data exist on the effect of these factors on course, prognostic, and risk factors for LBP in older adults.

In light of the aging population, it is important to understand the influence that comorbidities and lifestyle factors have on LBP in older adults. Robust evidence on the course of LBP in older adults, as well as risk and prognostic factors, will help health professionals manage LBP more effectively. Therefore, this study aimed to: (1) describe the course of LBP in older men over 2 years; (2) investigate whether the presence of comorbidities or lifestyle factors (ie, alcohol consumption, smoking, and physical activity) can predict the course of LBP in older men; (3) assess whether the presence of comorbidities or lifestyle factors can increase the risk of developing LBP in older men.

Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

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PAIN 158 (2017) 1571–1576

http://dx.doi.org/10.1097/j.pain.0000000000000952

2. Methods

2.1. Selection of subjects

Study participants were men aged 70 years and older in 2005 living in suburban Sydney, Australia, and included in the Concord Health and Ageing in Men Project (CHAMP).[6] The sampling frame was the New South Wales Electoral Roll for which enrolment is compulsory. Eligible men in the study area were sent a letter describing the study, and if they had a listed telephone number, were telephoned about 1 week later. Men without listed telephone numbers who did not respond to the first letter were sent a second invitation letter. Recruitment occurred sequentially across the geographic study area, with invitation letters being sent out each week during the recruitment period. Of the 3005 eligible men contacted, 1511 participated in the study (54%). An additional 194 eligible older men who lived in the study area heard about the study from friends or the media and asked to be in the study before receiving an invitation letter. The only exclusion criterion was living in a residential aged care facility. Baseline data were collected between January 2005 and June 2007 and follow-up data were collected 2 years later. The Concord Hospital Human Research Ethics Committee approved CHAMP. All participants provided written informed consent. The CHAMP study was funded by the National Health and Medical Research Council of Australia.

2.2. Low back pain assessment

Low back pain frequency and severity assessments were performed at baseline and at 24 months using a self-report questionnaire. The question about LBP frequency ("how often were you bothered by back pain in the past 12 months?") could be rated as: all the time, most of the time, some of the time, rarely, or never. LBP at baseline was defined as LBP that occurred some, most, or all of the time. The question about LBP severity ("when you have back pain, how bad it on average?") could be rated as: mild, moderate, and severe.

2.3. Predictive factors

The predictive factors included in the analyses were grouped into 4 domains:

(1) Sociodemographic measures included age, education (based on the question "since leaving school, have you obtained a trade qualification?"), marital status, living alone (based on the question "who else lives in your home?"), current paid employment (based on the question "are you currently in paid employment?"), country of birth (based on the question "in which country were you born?), and languages spoken at home (based on the question "what language do you usually speak at home?").

(2) Lifestyle factors included body mass index (BMI), alcohol consumption, smoking, and physical activity participation. We calculated BMI from height and weight measured during the clinical examination. We categorized BMI into 3 classes: (1) normal or underweight, (2) overweight, and (3) obese. Alcohol consumption was measured as continuous data of standard drinks per week (0-12 doses). Smoking was measured as the average number of packs of cigarettes smoked per day among current smokers. Physical activity was assessed using the Physical Activity Scale for Elderly questionnaire (PASE[23]). The PASE measures the level of physical activity for individuals aged 65 and older and assesses self-reported participation in occupational, household, and leisure physical activity over a period of 1 week. The PASE questionnaire consists of 24 questions in total and the overall score ranges from 0 to 315, where a score under 20 points represents low physical activity level, a score between 20 and 49 represents limited physical activity level, a score between 50 and 200 represents moderate physical activity level and a score over 200 represents high levels of physical activity.[23]

(3) Health factors included comorbidities and frailty. Comorbidities were assessed using a standardised questionnaire in which subjects reported whether a physician had ever told them that they had diabetes, thyroid dysfunction, osteoporosis, Paget disease, stroke, Parkinson disease, kidney stone, dementia, depression, epilepsy, hypertension, heart attack, angina, congestive heart failure, intermittent claudication, chronic obstructive lung disease, liver disease, vertebral fracture, and chronic kidney disease. Frailty was measured using the criteria recommended in the Cardiovascular Health Study (CHS).[11] Participants were considered frail if 3 or more of the following were present: weight loss, weakness, maximum grip strength, slow walking speed, and low activity level. Current weight was measured during the visit to the health care clinic, weakness (defined as being in the lowest quintile for grip strength according to data from the CHS) adjusted for BMI. Maximum grip strength was measured using the Jamar dynamometer, slow walking speed (defined as being in the lowest quintile for walking speed according to data from the CHS), adjusted for height (measured using a Harpenden stadiometer), and low activity level (defined as being in the lowest quintile on the PASE,[23] <73). Subjects were considered prefrail with 1 or 2 criteria and not frail (robust) without any criteria.

2.4. Statistical analyses

Descriptive statistics (mean and standard deviations for continuous variables, and frequencies and proportions for categorical variables) were used to summarise the clinical/demographic variables and also LBP status at baseline and follow-up. Multivariable regression models were built to identify the independent associations between the potential risk factors and developing LBP at follow-up among participants who did not report LBP at baseline, ie, LBP that occurred rarely or never (risk model). Separate multivariable regression models were used to assess if baseline pain, as well as the presence of comorbidities and lifestyle factors, would predict LBP persistence at the 24-month follow-up in participants who reported having LBP at baseline (prognostic model).

In both the risk and prognostic models, LBP was considered a binary outcome (presence of LBP coded as yes or no). For both the analyses, sociodemographic measures, participants' comorbidities, and lifestyle factors at baseline were considered to be covariates and were forced into the multivariable analysis in 3 blocks: sociodemographic measures, lifestyle factors, and comorbidities. Separate hierarchical linear regression models were used to determine the independent relationship between LBP and each of the 3 blocks of covariates. Alcohol consumption was measured as continuous data of standard drinks per week (0-12 doses). In both the risk and prognostic models, a variable called "number of comorbidities" was created by summing the 18 self-reported conditions listed in the study questionnaire. Frailty was analysed as a dichotomous variable: frail vs prefrail or robust. The main analyses only considered the frequency of LBP (pain all the time, most of the time, and some of the time). Sensitivity analyses were conducted by including only moderate to severe cases of LBP in the risk and prognosis multivariate models. Odds

ratios (OR) and 95% confidence intervals (CIs) were calculated and reported. Level of significance was set at 5%. STATA 13 (Stata Corp LP, College Station, TX) was used for all analyses.

3. Results

A total of 1685 subjects participated in the CHAMP study, of whom, 1367 (80%) completed the 24-month follow-up. The characteristics of the study sample are described in **Table 1**. Mean age at baseline was 77.0 years (SD: 5.5) and 60% (n = 1012) of the participants reported having LBP at baseline.

3.1. Course of Low back pain

A total of 1012 participants (60%) presented with LBP at baseline and 673 reported no LBP. For those with LBP at baseline, 83 (11%) reported pain all the time, 149 (19%) most of the time, and 548 (70%) some of the time. In terms of severity of

Table 1

Baseline characteristics of the study population (n = 1685).

Characteristics	Total (n = 1685)	No LBP (n = 673)	With LBP (n = 1012)
Age, mean (SD), y	76.92 (5.61)	76.9 (5.53)	76.84 (5.45)
Marital Status n (%)			
Married	1278 (74.96)	510 (75.87)	752 (74.37)
Living with a partner	31 (1.89)	12 (1.81)	19 (1.82)
Widowed	221 (12.93)	83 (12.34)	135 (13.35)
Divorced	65 (3.86)	18 (2.77)	46 (4.57)
Separated	24 (1.48)	11 (1.69)	13 (1.32)
Never married	86 (5.03)	39 (5.84)	47 (4.65)
Living alone*	318 (18.00)	120 (17.85)	195 (19.27)
Born in Australia†	849 (49.74)	315 (46.83)	529 (52.27)
Postschool qualification‡	915 (53.62)	358 (53.11)	554 (54.76)
English-speaking at home§	1059 (62.15)	406 (60.34)	646 (63.83)
Currently paid employment‖	129 (7.51)	51 (7.51)	76 (7.54)
Lifestyle factors			
BMI, mean (SD)¶	27.8 (4.05)	27.51 (3.96)	28.01 (4.17)
Alcohol consumption, mean (SD)#	1.7 (1.58)	1.6 (1.58)	1.8 (1.94)
Smokers, n (%)**	101 (5.97)	41 (6.16)	60 (6.05)
PASE, mean (SD)††	124.4 (62.24)	122.7 (61.83)	125.6 (62.62)
Health factors, n (%)			
Diabetes‡‡	308 (18.01)	126 (18.72)	182 (17.98)
High thyroid‡‡	39 (2.34)	11 (1.65)	28 (2.86)
Low thyroid‖	39 (2.37)	15 (2.38)	24 (2.49)
Paget's disease‡‡	34 (2.01)	7 (1.02)	27 (2.73)
Stroke‡‡	143 (8.54)	60 (8.95)	83 (8.26)
Parkinson's disease‡‡	31 (1.87)	7 (1.08)	24 (2.49)
Dementia‡‡	41 (2.48)	21 (3.17)	20 (1.96)
Depression‡‡	149 (8.95)	38 (5.74)	111 (11.03)
Epilepsy‡‡	20 (1.19)	11 (1.64)	9 (0.95)
Hypertension‡‡	780 (46.62)	299 (44.91)	481 (47.99)
Angina‡‡	293 (16.68)	88 (13.37)	205 (20.56)
Myocardial infarction‡‡	311 (18.65)	113 (17.04)	197 (19.73)
Heart failure‖	85 (5.02)	21 (3.21)	64 (6.49)
Intermittent claudication‖	157 (9.48)	44 (6.67)	113 (11.36)
Liver disease‡‡	36 (2.15)	13 (1.94)	23 (2.33)
Chronic obstructive lung disease‡‡	217 (12.72)	76 (11.41)	141 (13.91)
Cardiovascular disease‡‡	311 (18.22)	113 (16.83)	197 (19.54)
Chronic kidney disease‡‡	58 (3.45)	23 (3.56)	35 (3.57)
Kidney stone‡‡	213 (12.78)	65 (9.79)	148 (14.60)
Osteoporosis‡‡	118 (6.98)	31 (4.77)	87 (8.76)
Frailty§§	158 (9.55)	61 (9.24)	97 (9.33)

* Based on the question "who else lives in your home? No one/other."
† Based on the question "in which country were you born? Australia/other.
‡ Based on the question "since leaving school have you obtained a trade qualification?"
§ Based on the question "what language do you usually speak at home?"
‖ Based on the question "are you currently in paid employment?"
¶ Body-mass index: weight in kilograms divided by the square of the height in meters.
# Alcohol consumption: standard drinks per week (0-12 doses).
** Smoking: based on the question "Do you smoke cigarettes now?"
†† Physical activity: household and leisure items over a 1-week period.
‡‡ Based on the question "has a doctor or other health care provider ever told you that you had or have this condition?"
§§ Participants were considered frail if they reported 3 or more items (such as weight loss weakness/reduced muscular strength, slow walking speed and low activity level).
BMI, body mass index; LBP, low back pain; PASE, Physical activity participation.

pain, 231 participants (30%) reported mild pain, 429 (55%) reported moderate pain, and 121 (15%) reported severe pain. Of those with pain at baseline who were seen at the 2-year follow-up (n = 780), 452 (58%) still had pain at follow-up, and of those without pain at baseline who were seen at 2 years (n = 565), 157 (28%) reported pain at follow-up. Based on severity of LBP at baseline, 622 (37%) men with LBP had moderate to severe pain intensity, and 303 (61%) still reported having pain at the 24-month follow-up. Of those 1063 (63%) without pain at baseline, 134 (16%) reported moderate to severe pain intensity at follow-up.

3.2. Risk factors for developing low back pain

Odds ratio for lifestyle factors and comorbidities as risk factors for LBP are presented in **Table 2** For participants without LBP at baseline, number of comorbidities (OR = 1.17 for each additional comorbidity, 95% CI: 1.00-1.37; $P = 0.05$) was independently associated with the presence of LBP at follow-up. None of the lifestyle factors, sociodemographic measures, or frailty were independently associated with the risk of developing LBP at follow-up. When the data were limited to more severe categories of LBP at baseline, only BMI (OR = 1.80, 95% CI: 1.35-2.38, $P = 0.001$) increased odds of risk of LBP after 24 months.

3.3. Prognostic factors for low back pain

The logistic regression analyses (**Table 2**) revealed that speaking English at home (OR = 0.58, 95% CI: 0.35-0.96; $P = 0.03$) reduced the odds of still reporting LBP at follow-up, whereas the odds of persistent pain at 24 months significantly increased with each additional alcoholic drink/wk (OR = 1.10, 95% CI: 1.01-1.22; $P = 0.03$) and each additional unit of BMI (OR = 1.28, 95% CI: 1.04-1.60; $P = 0.02$), at baseline. None of the other predictors was associated with the prognosis of LBP. When the data were limited to more severe categories of LBP at baseline, only BMI (OR = 1.32, 95% CI: 1.00-1.75, $P = 0.05$) is associated with worse prognosis after 24 months.

4. Discussion

4.1. Statement of principal findings

Our study shows that LBP is common in older men and typically persistent with nearly 60% of our participants continuing to experience pain 2 years after entering the study. We also found that higher number of comorbidities increased the odds of developing LBP and lifestyle factors such as higher BMI and higher consumption of alcohol influenced its course.

4.2. Strengths and weaknesses of the study

The strengths of this study include a large sample of community-dwelling older Australian men aged 70 years and older and followed without systematic or specific interventions for a 2-year period, with high rates of follow-up (81%). Furthermore, the study included a comprehensive battery of self-reported and objective assessments, providing a unique opportunity to investigate risk and prognostic factors for LBP in older people. However, our study also has some limitations. First, our results are based on a community-dwelling sample and may not be applicable to older people with LBP who present to a health care provider. Second, only men were recruited and the extent to which these findings also apply to women is unclear. Third, men living in aged care facilities were excluded from the study, and it is also possible that community-dwelling men with more marked

Table 2

Multivariable regression models and estimates of the risk and prognosis of low back pain at 24-month follow-up primary analysis and sensitivity analyses.

Covariates	Main analysis				Sensitivity analysis			
	Risk		Prognosis		Risk		Prognosis	
	OR (95% CI)	P	OR (95% CI)	P	OR (95% CI)	P	OR (95% CI)	P
Sociodemographic measures								
Marital Status*	0.96 (0.73-1.28)	0.80	0.93 (0.81-1.08)	0.39	1.0 (0.85-1.27)	0.71	1.00 (0.82-1.20)	1.00
Living arrangement†	0.51 (0.19-1.40)	0.19	1.09 (0.65-1.84)	0.73	0.81 (0.39-1.69)	0.58	1.51 (0.76-3.03)	0.24
Born in Australia‡	0.71 (0.36-1.41)	0.33	1.28 (0.80-2.04)	0.29	1.25 (0.66-2.97)	0.49	0.92 (0.49-1.73)	0.79
Postschool qualification§	1.00 (0.99-1.00)	0.25	1.00 (0.98-1.02)	0.80	0.75 (0.50-1.11)	0.16	1.00 (0.99-1.02)	0.44
English-speaking at home‖	1.15 (0.56-2.31)	0.67	0.58 (0.35-0.96)	0.03	0.87 (0.44-1.68)	0.67	0.93 (0.48-1.80)	0.83
Currently paid employment#	1.00 (0.85-1.11)	0.65	1.05 (0.60-1.82)	0.86	0.98 (0.86-1.09)	0.62	0.81 (0.37-1.80)	0.61
Lifestyle factors								
BMI	1.28 (0.92-1.83)	0.14	1.28 (1.04-1.60)	0.02	1.80 (1.35-2.38)	0.001	1.32 (1.01-1.75)	0.05
Alcohol	1.00 (0.85-1.20)	0.86	1.10 (1.01-1.22)	0.03	1.00 (0.88-1.14)	0.98	1.10 (0.97-1.25)	0.13
Smoking**	0.68 (0.22-2.05)	0.49	2.00 (0.92-4.38)	0.08	1.12 (0.47-2.69)	0.79	1.78 (0.75-4.22)	0.19
Physical activity	1.00 (1.00-1.01)	0.54	1.00 (0.99-1.00)	0.80	1.00 (0.99-1.00)	0.94	1.00 (0.99-1.00)	0.68
No. of comorbidities	1.17 (1.01-1.37)	0.05	1.05 (0.95-1.60)	0.32	1.11 (0.98-1.26)	0.10	1.08 (0.95-1.22)	0.24
Frailty††	1.72 (0.66-4.50)	0.27	0.85 (0.44-1.65)	0.63	1.52 (0.67-3.45)	0.31	0.66 (0.30-1.47)	0.31

* Comparison groups were married vs others.
† Comparison groups were: living arrangement vs not living arrangement.
‡ Comparison groups were: from Australia vs others.
§ Comparison groups were: post-school qualification vs not post-school qualification.
‖ Comparison groups were speak English at home vs not speak English at home.
Comparison groups were currently in paid employment vs not currently in paid employment.
** Comparison groups were current smokers vs not current smokers.
†† Comparison groups were frail vs not frail.
OR, odds ratio.

activity limitations were less likely to participate in the study. Fourth, in our analyses we did not control for presence of previous episodes of LBP. The subgroup of men with pain at baseline and pain at follow-up were a mixture of first onset and recurrent LBP, and it is unclear if similar results would have been observed for men with a new episode of LBP, or those with persistent symptoms.

4.3. Strengths and weaknesses in relation to other studies

In our analysis of the course of LBP in older men, we found that over half of the participants with LBP still reported pain at the 2-year follow-up. The results are similar in the sensitivity analysis (based on severity of LBP) with 61% of the participants still reported having pain at the follow-up. These results are consistent with the results of other studies that evaluated the course of LBP in older adults. Rundell et al.[18] conducted a cohort study with 5239 adults aged 65 years or older with LBP, and found that 77% of them still reported ongoing pain at 12 months follow-up. Another cohort study[19] showed that 26% of 675 patients aged 55 years or older seeking primary care for a new episode of LBP reported persistent symptoms at 3 months follow-up.

Various risk factors for the development of LBP have been investigated, including lifestyle factors and comorbidities.[1,8] For instance, Stewart Williams et al.[20] recruited over 30,000 participants aged 50 years or older from different regions of the world and identified that lower education and multiple chronic morbidities were significantly associated with LBP onset. Our results are in agreement with this previous study, and have revealed that increasing numbers of comorbidities increased the risk of developing LBP. Another similarity was that in our analysis, none of the lifestyle factors were associated with the risk of developing LBP.

To date, there have only been 2 studies that have investigated the prognosis of LBP in older adults.[15,19] Only one[19] of them investigated similar factors to our study. Scheele et al.[19] enrolled 675 adults aged 55 and older in the Netherlands with a new episode of LBP and found that longer duration of LBP (OR = 1.8; 95% CI: 1.13.0), severity of pain (OR = 1.2; 95% CI: 1.1-1.3), and number of comorbidities (OR = 1.2; 95% CI: 1.1-1.4) were associated with persistent LBP assessed at 3 months. In contrast, we did not find any association between comorbidities and prognosis of LBP over 24 months. Possibly the differences in the sample may partially explain these different findings because the Dutch cohort enrolled a sample of older men and women seeking primary care with higher levels of pain and the participants of the current study were men selected from the community.

Our findings support the idea that research on predictors of LBP in young adults may not be not generalisable to older adults. One systematic review[21] on risk factors for LBP in younger adults investigated similar factors to our study, such as lifestyle factors (BMI, physical activity, smoking, and alcohol consumption) and comorbidities, and found smoking (OR = 1.88, 95% CI: 1.32-2.69) increased the risk of a future episode. By contrast, none of the lifestyle factors were associated with the risk developing LBP in older adults in our study. Similarly, one recent systematic review[22] investigated prognostic factors in populations younger than our sample, and found a markedly different list of prognostic factors to us: older age, psychological or psychosocial stress and physically heavy work. Together, these differences underscore the importance of longitudinal research in older adults.

In our study, we investigated several lifestyle factors and found associations between some of these factors and prognosis, but not onset of LBP. One of these factors was higher BMI, which is generally associated with LBP.[7,8] The results are similar in the sensitivity analysis (OR = 1.32, 95% CI: 1.00-1.75, $P = 0.05$). However, the actual path between these conditions remains controversial. Some studies have shown that BMI is associated with poor recovery from LBP,[7,8] whereas others have failed to observe any association between BMI and LBP.[13] Another lifestyle factor associated with the prognosis of LBP in our study was alcohol consumption, which increased the odds of worse outcomes for men with LBP. To our knowledge, this is the first study that has examined alcohol consumption as a prognostic factor in older LBP patients, given most of the previous studies only included younger adults[13] and no association was found (OR = 0.87, 95% CI: 0.61-1.63). The previous studies that investigated this association in general population showed that alcohol consumption seems to be associated with LBP only in people with alcohol consumption dependence. A possible explanation of our results is that men with more poorly controlled pain would use alcohol as a way of dealing with the pain.

We also found that men who speak English at home were less likely to report pain at 2 years compared with those who do not speak English. This result is similar to a cohort study[5] involving 406 patients (32% born outside Australia) presenting to primary care with LBP. In that study, the results showed that participants who were born outside of Australia recovered more slowly than those who were born in Australia (Hazard Ratio = 0.51, 95% CI: 0.33-0.78). Our current study included an ethnically heterogeneous population, with 44% of participants (n = 751) born in a non-English-speaking country such as Italy, Greece, and China. Communication barriers could affect participant's ability to understand about their condition, resulting in worse control and management of their care.[10,15] However, not speaking English at home does not necessarily indicate poor communication skills, thus it is possible that other factors may be influencing the prognosis of these patients, such as cultural health beliefs, access to care and patients' expectations about their condition.

In summary, we found that the number of comorbidities was associated with increased risk of developing LBP among older men. Furthermore, in those with LBP, higher alcohol consumption, higher BMI and not speaking English at home seem to be associated with worse prognosis. There were important differences between these findings and findings from the general population. Our results on the course, as well as the risk and prognostic factors, of LBP in older men could help better inform health care professionals about potential factors that may affect the course of the condition.

Conflict of interest statement

The authors have no conflicts of interest to declare.

The CHAMP study was supported by National Health and Medical Research Council of Australia (project grant no. 301916) and Ageing and Alzheimer's Research Foundation. P. C.S. Parreira is supported by CAPES (Coordenação de Aperfeiçoamento de Pessoal de Nível Superior), Brazil. G. C. Machado is supported by the Australian Department of Education and Training. C. G. Maher is supported by National Health and Medical Research Council of Australia. M. L. Ferreira is supported by the Sydney Medical Foundation, Sydney Medical School.

Acknowledgements

Author contributions: All authors were involved in the design of the study. M. L. Ferreira and G. C. Machado conducted the statistical analyses. P. C.S. Parreira, M. L. Ferreira and C. G. Maher wrote the first draft. All authors contributed to further drafts. All authors had full access to the data, specifically, the statistical reports and tables arising from the data, and take responsibility for the integrity of the data and accuracy of the data analysis. All authors have approved the final version of the manuscript submitted for publication.

Article history:
Received 3 January 2017
Received in revised form 1 May 2017
Accepted 10 May 2017
Available online 16 May 2017

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Chapter Five

Back Schools for chronic non-specific low back pain

Chapter Five has been presented as:

Parreira P, Heymans MW, van Tulder MW, Esmail R, Koes BW, Poquet N, Lin CC, Maher CG. *Back Schools for chronic non-specific low back pain*. Cochrane Database Syst Rev. 2017 Aug 3; 8:CD011674

Statement from co-authors confirming authorship contribution of the PhD Candidate

The co-authors of the paper: *"Parreira P, Heymans MW, van Tulder MW, Esmail R, Koes BW, Poquet N, Lin CC, Maher CG. Back Schools for chronic non-specific low back pain. Cochrane Database Syst Rev. 2017 Aug 3; 8:CD011674"* confirm that Patricia C S Parreira has made the primary contribution to this study in each of the following areas:

• Conception and design of the research

• Interpretation of findings

• Writing of the manuscript and critical appraisal of content

In addition to the statements above, in cases where I am not the corresponding author of a published item, permission to include the published material has been granted by the corresponding author.

Patricia do Carmo Silva Parreira _____ Date: 08/07/2018

As supervisor for the candidature upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

Professor Chris Maher_____ Date: 08/07/2018

Back Schools for chronic non-specific low back pain

Review information

Review type: Intervention

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Citation example: Parreira P, Heymans MW, van Tulder MW, Esmail R, Koes BW, Poquet N, Lin C-WC, Maher CG. Back Schools for chronic non-specific low back pain. Cochrane Database of Systematic Reviews 2017 , Issue 7 . Art. No.: CD011674. DOI: 10.1002/14651858.CD011674.pub2 .

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Dates

Assessed as Up-to-date:	15 November 2016
Date of Search:	15 November 2016
Next Stage Expected:	31 July 2022
Protocol First Published:	Issue 5 , 2015
Review First Published:	Issue 7 , 2017
Last Citation Issue:	Issue 7 , 2017

What's new

Date	Event	Description
15 November 2016	New citation: conclusions changed	In this update, we identified 19 additional studies for a total of 30 included studies. The conclusions of this review are not in agreement with the previous Cochrane review (Heymans 2004). In the previous Cochrane review, the authors concluded that there was moderate evidence suggesting that Back Schools, in an occupational setting, reduced pain and improved function and return-to-work status, in the short and intermediate term, compared to exercises, manipulation, myofascial therapy, advice, placebo, or waiting-list controls, for people with chronic and recurrent low back pain. In this update, we found low- to very low-quality evidence for all treatment comparisons, outcomes, and follow-up periods investigated.
10 September 2015	Updated	Four authors joined the review team (P Parreira, N Poquet, C Maher, and C Lin), and one of the original authors is no longer involved (C Bombardier). We made the following methodological changes: We included quasi-randomised controlled trials as well as randomised controlled trials. The primary outcomes were pain and disability. The secondary outcomes were work status and adverse events. Finally, we stratified 'other treatments' into medical care, passive physiotherapy, and exercise because we considered these treatments to be sufficiently different that they should be evaluated separately.

History

Date	Event	Description

Abstract

Background

Many people with low back pain (LBP) become frequent users of healthcare services in their attempt to find treatments that minimise the severity of their symptoms. Back School consists of a therapeutic programme given to groups of people that includes both education and exercise. However, the content of Back School has changed over time and appears to vary widely today. This review is an update of a Cochrane review of randomised controlled trials (RCTs) evaluating the effectiveness of Back School. We split the Cochrane review into two reviews, one focusing on acute and subacute LBP, and one on chronic LBP.

Objectives

The objective of this systematic review was to determine the effect of Back School on pain and disability for adults with chronic non-specific LBP; we included adverse events as a secondary outcome. In trials that solely recruited workers, we also examined the effect on work status.

Search methods

We searched for trials in the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, Embase, CINAHL, two other databases and two trials registers to 15 November 2016. We also searched the reference lists of eligible papers and consulted experts in the field of LBP management to identify any potentially relevant studies we may have missed. We placed no limitations on language or date of publication.

Selection criteria

We included only RCTs and quasi-RCTs evaluating pain, disability, and/or work status as outcomes. The primary outcomes for this update were pain and disability, and the secondary outcomes were work status and adverse events.

Data collection and analysis

Two review authors independently performed the 'Risk of bias' assessment of the included studies using the 'Risk of bias' assessment tool recommended by The Cochrane Collaboration. We summarised the results for the short-, intermediate-, and long-term follow-ups. We evaluated the overall quality of evidence using the GRADE approach.

Main results

For the outcome pain, at short-term follow-up, we found very low-quality evidence that Back School is more effective than no

treatment (mean difference (MD) -6.10, 95% confidence interval (CI) -10.18 to -2.01). However, we found very low-quality evidence that there is no significant difference between Back School and no treatment at intermediate-term (MD -4.34, 95% CI –14.37 to 5.68) or long-term follow-up (MD -12.16, 95% CI -29.14 to 4.83). There was very low-quality evidence that Back School reduces pain at short-term follow-up compared to medical care (MD -10.16, 95% CI –19.11 to -1.22). Very low-quality evidence showed there to be no significant difference between Back School and medical care at intermediate-term (MD -9.65, 95% CI -22.46 to 3.15) or long-term follow-up (MD -5.71, 95% CI –20.27 to 8.84). We found very low-quality evidence that Back School is no more effective than passive physiotherapy at short-term (MD 1.96, 95% CI –9.51 to 13.43), intermediate-term (MD -16.89, 95% CI -66.56 to 32.79), or long-term follow-up (MD -12.86, 95% CI –61.22 to 35.50). There was very low-quality evidence that Back School is no better than exercise at short- term follow-up (MD -2.06, 95% CI –14.58 to 10.45). There was low-quality evidence that Back School is no better than exercise at intermediate-term (MD -4.46, 95% CI –19.44 to 10.52) and long-term follow-up (MD 4.58, 95% CI –0.20 to 9.36).

For the outcome disability, we found very low-quality evidence that Back School is no more effective than no treatment at intermediate-term (MD –5.92, 95% CI –12.08 to 0.23) and long-term follow-up (MD -7.36, 95% CI -22.05 to 7.34); medical care at short-term (MD –1.19, 95% CI –7.02 to 4.64) and long-term follow-up (MD –0.40, 95% CI –7.33 to 6.53); passive physiotherapy at short-term (MD 2.57, 95% CI –15.88 to 21.01) and intermediate-term follow-up (MD 6.88, 95% CI -4.86 to 18.63); and exercise at short-term (MD -1.65, 95% CI –8.66 to 5.37), intermediate-term (MD 1.57, 95% CI –3.86 to 7.00), and long-term follow-up (MD 4.54, 95% CI -4.44 to 13.52). We found very low-quality evidence of a small difference between Back School and no treatment at short-term follow-up (MD –3.38, 95% CI –6.70 to –0.05) and medical care at intermediate-term follow-up (MD –6.34, 95% CI –10.89 to –1.79). Still, at long-term follow-up there was very low-quality evidence that passive physiotherapy is better than Back School (MD 9.60, 95% CI 3.65 to 15.54).

Few studies measured adverse effects. The results were reported as means without standard deviations or group size was not reported. Due to this lack of information, we were unable to statistically pool the adverse events data. Work status was not reported.

Authors' conclusions

Due to the low- to very low-quality of the evidence for all treatment comparisons, outcomes, and follow-up periods investigated, it is uncertain if Back School is effective for chronic low back pain. Although the quality of the evidence was mostly very low, the results showed no difference or a trivial effect in favour of Back School. There are myriad potential variants on the Back School approach regarding the employment of different exercises and educational methods. While current evidence does not warrant their use, future variants on Back School may have different effects and will need to be studied in future RCTs and reviews.

Plain language summary

Back School for the treatment of chronic low back pain

Background

Many people with low back pain (LBP) seeking treatments that minimise the severity of their symptoms become frequent users of healthcare services. Back School consists of a therapeutic programme given to groups of people that includes both education and exercise. Since its introduction in 1969, the Swedish Back School has frequently been used in the treatment of LBP. However, the content of Back School has changed over time and appears to vary widely today.

Review question

We reviewed the evidence on the effects of Back School on pain and disability in adults with LBP with no specific cause lasting more than 12 weeks compared to no treatment, medical care, physiotherapist-applied treatment, or exercise. We included adverse events as a secondary outcome. In trials that only recruited workers, we also examined the effect on work status.

Study characteristics

In this update we searched for trials, both published and unpublished, to 15 November 2016. We included 30 trials with 4105 participants comparing Back School to no treatment, medical care, passive physiotherapy (physiotherapist-applied treatment), or exercise therapy. All studies included a similar population of people with chronic non-specific LBP.

Key results

Regardless of the comparison used (as well as the outcomes investigated), the results of the meta-analysis showed no difference or a trivial effect in favour of Back School. Due to a lack of information on adverse effects and work status, we were unable to statistically pool the data.

Quality of evidence

Due to the low- to very low-quality evidence for all treatment comparisons, outcomes, and follow-up periods investigated, it is uncertain if Back School is effective for chronic low back pain.

Background

See glossary of terms in Appendix 1.

Description of the condition

Low back pain (LBP) is a major problem worldwide, and the associated disability is responsible for a significant personal

burden (van Tulder 2006). The Global Burden of Disease Study suggests that LBP is one of the 10 leading causes of disease burden globally (Murray 2013; Vos 2010). Many people with LBP become frequent users of healthcare services in their attempt to find treatments that minimise the severity of their symptoms.

Exercise therapy is commonly advised for people with LBP, and it is recommended in clinical practice guidelines as an effective treatment for chronic LBP (European Guidelines 2006). A Cochrane systematic review on this topic also concluded that exercise therapy is effective in decreasing pain and improving function in adults with chronic LBP (Hayden 2005). Education has been recommended in clinical practice guidelines for chronic LBP (European Guidelines 2006). Supervised exercise therapy associated with an educational component has been considered to be one of the most effective interventions in reducing pain and disability in people with chronic LBP (Airaksinen 2006; van Tulder 2006).

Back School is one treatment that provides both exercise and education for the treatment of people with chronic LBP. The original Swedish Back School was introduced by Zachrisson-Forssell in 1969. It was designed to reduce pain and prevent recurrences of LBP episodes (Forssell 1980; Forssell 1981). Back School was a therapeutic programme including information on the anatomy of the back, biomechanics, optimal posture, ergonomics, and back exercises. Since the introduction of the Swedish Back School, the content and length of the method have changed and appear to vary widely today.

This review is an update of a previously conducted Cochrane review of the effectiveness of Back School for chronic non-specific LBP. The previous Cochrane review was published in 2004 and concluded that Back School seemed to be more effective than other treatments, placebo, or waiting-list controls for improving pain, functional status, and return to work (Heymans 2004). Since the completion of this review, new trials about Back School have been published (Andrade 2008; Cecchi 2010a; Costantino 2014; Devasahayam 2014; Donzelli 2006; Dufour 2010; Durmus 2014; Garcia 2013; Heymans 2006; Jaromi 2012; Meng 2009; Morone 2011; Morone 2012; Nentwig 1990; Paolucci 2012a; Paolucci 2012b; Ribeiro 2008; Sahin 2011; Tavafian 2007). Given this substantial amount of new data, and developments in systematic review methods, a revision of the 2004 Cochrane review was needed to provide clinicians and patients up-to-date information about the effects of this intervention. Our aim was therefore to perform an update on this topic in order to provide accurate and robust information on the effectiveness of the Back School approach for chronic non-specific LBP, as compared to no treatment, medical care, passive physiotherapy, or exercise therapy.

Description of the intervention

The original Swedish Back School was introduced by Zachrisson-Forssell in 1969. It was meant to reduce pain and prevent recurrences of episodes of LBP (Forssell 1980; Forssell 1981). Back School was a therapeutic programme including information on the anatomy of the back, biomechanics, optimal posture, ergonomics, and back exercises and was given to groups of patients. The aim was to reduce back pain and teach people to care for their own backs and back pain in an active way should back pain recur.

How the intervention might work

Back School is a combination of exercises and education, where lessons are given to groups of patients, supervised by a physical therapist or medical specialist. According to the European guidelines (Airaksinen 2006), the combination of exercise programmes and education seems to be the most promising approach for the management of chronic non-specific LBP. Theoretical information could help patients understand their condition and learn how to modify their behaviour with regard to LBP. People with chronic non-specific LBP often have maladaptive thoughts, feelings, and beliefs, which have an important role in their experience of LBP (Parsons 2007). Exercise therapy is probably the most commonly used intervention for the treatment of people with chronic non-specific LBP. It is reported in the literature as effective in decreasing pain and improving function (Hayden 2005). Treatment that combines both interventions has the potential to improve pain and disability in people with chronic non-specific LBP.

Why it is important to do this review

This review is an update of a previously conducted Cochrane review of randomised controlled trials on the effectiveness of Back School (Heymans 2004). We split this review into two reviews, one focusing on acute and subacute LBP, and one on chronic LBP. This review evaluated the effectiveness of Back School for chronic non-specific LBP. In previous reviews it was not possible to statistically pool the data because of the heterogeneity of the included studies. Conclusions were generated on the basis of the methodological quality scores of the studies, assessed using a generally accepted criteria list, in combination with a best-evidence synthesis (van Tulder 2003). Since 2011, a number of new RCTs have been published evaluating the effectiveness of Back School. Method guidelines for Cochrane reviews have also been published by The Cochrane Collaboration (Higgins 2011) and in the field of back pain (Furlan 2015). These were also implemented in the current updated review.

Objectives

The objective of this systematic review was to determine the effect of Back School on pain and disability for adults with chronic non-specific LBP; we included adverse events as a secondary outcome. In trials that solely recruited workers, we also examined the effect on work status.

Methods

Criteria for considering studies for this review

Types of studies

We included only randomised controlled trials (RCTs) and quasi-RCTs.

Types of participants

We included studies evaluating people with chronic (more than 12 weeks' duration) non-specific LBP, aged 18 to 70 years. Low back pain is defined as pain localised below the scapulae and above the cleft of the buttocks; non-specific indicates that no specific cause was detected, such as infection, neoplasm, metastasis, osteoporosis, fracture, or inflammatory arthritis. We did not include trials enrolling participants with pregnancy-related LBP.

Types of interventions

We included studies in which one of the treatments consisted of a Back School-type of intervention. We included trials that used a clear contrast for the Back School intervention, such as usual care, waiting list, or other interventions (e.g. exercise therapy or manipulation). Additional interventions were allowed. However, if the Back School was part of a larger multidisciplinary treatment programme, we only included the study if a contrast existed for the Back School. For example, a study that compared Back School plus a fitness programme against a fitness programme was included, but a study that compared Back School plus fitness programme against a waiting list was not. Trials that studied the effectiveness of Back School in workers or non-workers without low back pain at study onset were not included because they concerned primary prevention of LBP.

Technique (index dose):

We classified the intensity of the technique as follows.

- Intensive: when the length of the session was greater than or equal to 20 hours (intervention time)
- Non-intensive: when the length of the session was less than 20 hours (intervention time)
- Not specified

Types of outcome measures

We included trials that reported outcomes for short-term (less than three months), intermediate-term (three to six months), and long-term (more than six months) follow-up.

Primary outcomes

1. Pain (e.g. measured by visual analogue scale or numerical rating scale)
2. Disability (e.g. measured by Oswestry Disability Index (ODI) or Roland-Morris Disability Questionnaire (RMDQ))

Secondary outcomes

1. Work status in trials that solely recruited workers (e.g. days of sick leave)
2. Adverse events (reported by the physiotherapists on standardised forms)

Search methods for identification of studies

Electronic searches

We used the search methods developed by the Cochrane Back and Neck Review Group and Chapter 6 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Furlan 2015; Higgins 2011). The strategies were developed and updated by the Information Specialist of the Back and Neck Review Group.

We searched for trials in the following databases to 15 November 2016:

- Cochrane Central Register of Controlled Trials (CENTRAL, which also includes the Back and Neck Group Trials Register) (the Cochrane Library, Issue 10, 2016);
- MEDLINE (OvidSP; Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R); 1946 to 15 November 2016);
- Embase (Ovid SP, 1980 to 2016 Week 46);
- Cumulative Index to Nursing and Allied Health Literature (CINAHL) (EBSCO, 1981 to 15 November 2016);
- PsycINFO (Ovid SP, 2002 to November Week 1 2016);
- ClinicalTrials.gov (clinicaltrials.gov/);
- World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) (apps.who.int/trialsearch/);
- PubMed (www.ncbi.nlm.nih.gov/pubmed).

We added CINAHL and PsycINFO to the search in 2007 and the clinical trials registries in 2011; we searched these from inception to current. We added MEDLINE In-Process & Other Non-Indexed Citations in 2015. We searched PubMed in August 2015 to capture any studies published within the previous year using the strategy recommended by Duffy 2014. In 2016, we searched MEDLINE (Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R)), which allows multiple sets of MEDLINE databases to be searched at one time.

The search strategies can be found in Appendix 2.

Searching other resources

We screened reference lists of relevant reviews and included studies, and consulted experts in the field of LBP management to identify any potentially relevant studies we may have missed.

Data collection and analysis

For each of the steps, two review authors (PP and NP) independently selected new studies, assessed risk of bias, and

extracted data (using a standardised form). Any disagreements were resolved by consensus or by bringing in a third review author if disagreements persisted (CM).

Selection of studies

For this update, we first reassessed the included studies from the original review to ensure that they met our revised inclusion criteria. Following the same process as in the original review and previous update, two review authors (PP and NP) first screened the titles and abstracts of the new studies. The full texts of all potentially relevant studies were then retrieved for the final selection of eligible studies.

Data extraction and management

Two review authors (PP and NP) independently extracted the data using standardised data extraction forms. We collected the following information:

- participant characteristics (patient source or setting, study inclusion criteria, duration of LBP episode);
- intervention characteristics (description and types of Back School, duration and number of treatment sessions, intervention delivery type, and co-interventions); and
- outcome data (pain intensity, disability, work status, adverse events);

When several time points fell within the same category, we used the time point closest to six weeks for the short term, four months for the intermediate term, and 12 months for the long term.

Assessment of risk of bias in included studies

Two review authors (PP and NP) independently assessed the risk of bias in included studies. We employed a consensus method to resolve disagreements, consulting a third review author (CM) if disagreement persisted. We used the Cochrane Back and Neck 'risk of bias' criteria (Table 1 and Table 2) (Furlan 2015).

Measures of treatment effect

The primary outcome measures were continuous (pain and disability); the secondary outcome measures (work status and adverse events) were mainly dichotomous. For all continuous outcomes, we quantified the treatment effects with the mean difference (MD). To accommodate the different scales used for these outcomes, we converted outcomes to a common 0-to-100 scale. We also expected to encounter dichotomous outcomes such as return to work; in such cases we calculated risk ratios (RR) of experiencing the positive outcome. We used effect sizes and 95% confidence intervals (CI) as a measure of treatment effect.

Unit of analysis issues

If trials were sufficiently homogenous, we conducted a meta-analysis for these follow-up time points: short (within three months after randomisation), intermediate (at least three months but within 12 months after randomisation), and long term (12 months or longer after randomisation). When multiple time points fell within the same category, we used the one that was closer to the end of treatment, 6 months or 12 months.

Dealing with missing data

We emailed the authors of each study requesting any necessary data that were not comprehensively reported in the manuscript. We also estimated data from graphs in cases where this information was not presented in tables or text. If the standard deviation was not reported, we calculated it from confidence intervals or standard errors (if available). If no measure of variability was presented anywhere in the text, we estimated the standard deviation from the most similar trial in the review, taking the risk of bias of individual studies into consideration.

Assessment of heterogeneity

We based the assessment of heterogeneity on visual inspections of the forest plots (e.g. overlapping confidence intervals) and more formally by the Chi^2 test and the I^2 statistic, as recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Assessment of reporting biases

To avoid potential language bias, we applied no language restriction to the searches.

Data synthesis

Regardless of whether there were sufficient data available to use quantitative analyses to summarise the data, we assessed the overall quality of the evidence for each outcome. We used the GRADE approach, as recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), and adapted in the updated Cochrane Back and Neck Review Group method guidelines (Furlan 2015). The GRADE approach to evidence synthesis can be found in Appendix 3.

Subgroup analysis and investigation of heterogeneity

We stratified the analyses based upon the duration of follow-up reported for each outcome (i.e. short term, intermediate term, and long term).

Sensitivity analysis

We planned sensitivity analyses to see if the overall results on effectiveness between comparison groups changed when in

the studies of high risk of bias, defined as fulfilling five or more criteria out of the 13.

Results

Description of studies

Results of the search

The search retrieved 307 trials after duplicates were removed (Figure 1). After the selection and discussion step, based on title, keyword, abstract, and full text screening, both review authors agreed that 19 studies (20 references) met the inclusion criteria (Andrade 2008; Cecchi 2010a; Costantino 2014; Devasahayam 2014; Donzelli 2006; Dufour 2010; Durmus 2014; Garcia 2013; Heymans 2006; Jaromi 2012; Meng 2009; Morone 2011; Morone 2012; Nentwig 1990; Paolucci 2012a; Paolucci 2012b; Ribeiro 2008; Sahin 2011; Tavafian 2007). We found one study that was a protocol for an included study (Garcia 2013). We included 11 studies (15 references) from the previous review (Berwick 1989; Dalichau 1999; Donchin 1990; Hurri 1989; Keijsers 1989; Keijsers 1990; Klaber Moffett 1986; Lankhorst 1983; Lønn 1999; Penttinen 2002; Postacchini 1988). We included a total of 30 studies (35 references) in this update. An additional search for ongoing or registered trials in ClinicalTrials.gov and the WHO ICTRP retrieved one record (IRCT201010184251N2). We consulted experts in the field of LBP research but did not identify any new studies. The most recent search performed on 15 November 2016 retrieved two studies that fulfilled the inclusion criteria (Garcia 2016; Paolucci 2016), and we added them to the 'awaiting classification' section to be incorporated in the next review update.

Included studies

We included 30 studies with a total of 4105 participants. The study sample sizes ranged from 37 to 360 participants (mean = 128). Ten studies were not included in the meta-analysis because they lacked necessary data (Dalichau 1999; Donchin 1990; Dufour 2010; Hurri 1989; Keijsers 1990; Morone 2011; Morone 2012; Nentwig 1990; Paolucci 2012a; Postacchini 1988).

Design

Of the 30 studies included in this review, only one study was a quasi-RCT (Donzelli 2006).

Types of studies

We identified the following comparisons in this review.

1. Ten trials compared Back School with no treatment (Andrade 2008; Dalichau 1999; Donchin 1990; Hurri 1989; Keijsers 1989; Keijsers 1990; Lønn 1999; Meng 2009; Nentwig 1990; Postacchini 1988).
2. Seven trials compared Back School with medical care (Berwick 1989; Morone 2011; Morone 2012; Paolucci 2012a; Paolucci 2012b; Ribeiro 2008; Tavafian 2007).
3. Four trials compared Back School with passive physiotherapy (Cecchi 2010a; Jaromi 2012; Lankhorst 1983; Postacchini 1988).
4. Eleven trials compared Back School with exercises (Costantino 2014; Devasahayam 2014; Donchin 1990; Donzelli 2006; Dufour 2010; Durmus 2014; Garcia 2013; Heymans 2006; Klaber Moffett 1986; Penttinen 2002; Sahin 2011).

Two trials had three treatment arms (Donchin 1990; Postacchini 1988), and we included both treatment contrasts.

Study population

Eleven studies included a homogeneous population of LBP patients without radiation (Andrade 2008; Berwick 1989; Cecchi 2010a; Costantino 2014; Devasahayam 2014; Donzelli 2006; Durmus 2014; Garcia 2013; Lankhorst 1983; Meng 2009; Sahin 2011), while 17 studies did not specify if participants had radiating symptoms or not, and five studies included a mixed population of patients with and without radiating symptoms (Dufour 2010; Heymans 2006; Jaromi 2012; Morone 2011; Tavafian 2007). Eight studies reported no data on the sex or age of the groups evaluated (Andrade 2008; Devasahayam 2014; Donzelli 2006; Keijsers 1990; Meng 2009; Nentwig 1990; Paolucci 2012a; Postacchini 1988); three studies included women only (Durmus 2014; Hurri 1989; Linton 1989); and one study included men only (Dalichau 1999). All trials included participants with chronic symptoms (LBP persisting for 12 weeks or more) exclusively.

Primary outcomes

Pain intensity

Seventeen studies measured pain intensity with a visual analogue scale or a numerical rating scale from 0 to 10 (Andrade 2008; Devasahayam 2014; Donzelli 2006; Dufour 2010; Durmus 2014; Garcia 2013; Heymans 2006; Jaromi 2012; Keijsers 1989; Klaber Moffett 1986; Meng 2009; Morone 2011; Morone 2012; Paolucci 2012a; Postacchini 1988; Ribeiro 2008; Sahin 2011). The other instruments were: pain rating (Cecchi 2010a; Dalichau 1999), pain index (Hurri 1989; Keijsers 1990; Morone 2011), McGill Pain Scale, pain severity subscale (Paolucci 2012b), subscale of 36-Item Short Form Health Survey (SF-36) (Tavafian 2007), and mean pain (Lankhorst 1983). One study created their own instrument (Nentwig 1990). All scales were converted to a 0-to-100 scale.

Disability

Nineteen studies measured disability (Andrade 2008; Cecchi 2010a; Costantino 2014; Devasahayam 2014; Donchin 1990; Donzelli 2006; Dufour 2010; Durmus 2014; Garcia 2013; Heymans 2006; Hurri 1989; Klaber Moffett 1986; Lønn 1999; Meng 2009; Morone 2011; Morone 2012; Penttinen 2002; Ribeiro 2008; Sahin 2011). Seven studies measured disability

with the Roland-Morris Disability Questionnaire (Andrade 2008; Cecchi 2010a; Costantino 2014; Devasahayam 2014; Dufour 2010; Garcia 2013; Heymans 2006). Nine studies measured disability using the Oswestry Disability Index (Donchin 1990; Donzelli 2006; Durmus 2014; Hurri 1989; Klaber Moffett 1986; Morone 2011; Morone 2012; Penttinen 2002; Sahin 2011); one study used the Low Back Disability Scale (Lønn 1999); and one study used the Hannover Functional Ability Questionnaire (Meng 2009). All scales were converted to a 0-to-100 scale.

Secondary outcomes

Return to work

Three studies measured return to work (Dalichau 1999; Heymans 2006; Keijsers 1990). Due to insufficient information, we were unable to statistically pool the data.

Adverse events

Three studies measured adverse effects (Dufour 2010; Garcia 2013; Heymans 2006). All studies either reported means without standard deviations or did not report group size; we were therefore unable to statistically pool the data.

Excluded studies

We excluded 19 studies (20 references) in the full –text assessment for eligibility. Of the 19 excluded full-text articles, six studies did not consider Back School as the intervention (Demoulin 2006; Härkäpää 1989; Härkäpää 1990; Linton 1989; Tavafian 2008; Yang 2010). In one study the results were for a single group (Sadeghi-Abdollahi 2012). In another study each group was assessed once (the control group at the beginning of the programme, the Back School group at the end) (Morrison 1988). In three studies, the Back School intervention consisted of education only, without exercises (Cecchi 2010b; Indahl 1998; Maul 2005; Mele 2006). In one study the Back School intervention was not a clear contrast for the control group (Meng 2011). In six studies, the average time of symptoms in the inclusion criteria was characterised as acute LBP (Bergquist 1977; Herzog 1991; Hsieh 2002; Indahl 1995; Leclaire 1996; Lindequist 1984).

Risk of bias in included studies

The results from the 'Risk of bias' assessment for the individual studies are summarised in Figure 2. We considered 10% of the studies to have a low risk of bias. Due to the small number of studies with low risk of bias, it was not possible to run a sensitivity analysis as planned.

Allocation (selection bias)

Eleven studies described an appropriate method of randomisation (Andrade 2008; Costantino 2014; Donchin 1990; Dufour 2010; Durmus 2014; Garcia 2013; Heymans 2006; Klaber Moffett 1986; Lønn 1999; Paolucci 2012a; Ribeiro 2008). Only seven studies were at low risk of bias for allocation concealment (Dufour 2010; Durmus 2014; Heymans 2006; Klaber Moffett 1986; Paolucci 2012a; Ribeiro 2008; Sahin 2011).

Blinding (performance bias and detection bias)

Due to the nature of the intervention, none of the included studies blinded participants or care providers. Nine of the included studies blinded outcome assessment (Andrade 2008; Cecchi 2010a; Devasahayam 2014; Dufour 2010; Garcia 2013; Heymans 2006; Jaromi 2012; Ribeiro 2008; Sahin 2011).

Incomplete outcome data (attrition bias)

Most of the included studies (86%) had a good rate of follow-up, with less than 20% withdrawals and dropouts.

Selective reporting (reporting bias)

One of the included studies had a published protocol (Garcia 2013). We scored all studies as at unclear risk of reporting bias, as we could not compare prespecified outcomes with reported ones.

Other potential sources of bias

We considered all studies as having a low risk of other potential sources of bias.

Effects of interventions

See: Summary of main results, Summary of findings table 1; Summary of findings table 2; Summary of findings table 3; Summary of findings table 4

Effectiveness of Back School

Comparison 1: Back School versus no treatment

Ten trials compared Back School with no treatment for chronic LBP (Andrade 2008; Dalichau 1999; Donchin 1990; Hurri 1989; Keijsers 1989; Keijsers 1990; Lønn 1999; Meng 2009; Nentwig 1990; Postacchini 1988). Four trials provided insufficient information and were therefore not included in the analysis (Donchin 1990; Hurri 1989; Nentwig 1990; Postacchini 1988).

In the meta-analysis for the outcome pain, based on six trials (Andrade 2008; Dalichau 1999; Keijsers 1989; Keijsers 1990; Lankhorst 1983; Meng 2009), there was very low-quality evidence (downgraded due to risk of bias, inconsistency, and publication bias) that Back School reduces pain compared with no treatment at short-term follow-up (MD -6.10, 95% CI –10.18 to -2.01; I^2 = 19%). At intermediate-term follow-up, four trials provided very low-quality evidence (downgraded due to

imprecision, risk of bias, and publication bias) that there was no substantial difference between Back School and no treatment (MD -4.34, 95% CI –14.37 to 5.68; I^2 = 71%) (Andrade 2008; Keijsers 1990; Lankhorst 1983; Lønn 1999). Based on three trials (Dalichau 1999; Lankhorst 1983; Lønn 1999), there was very low-quality evidence (downgraded due to imprecision, risk of bias, inconsistency, and publication bias) that Back School was no better than no treatment at long-term follow-up (MD -12.16, 95% CI -29.14 to 4.83; I^2 = 84%) (Analysis 1.1).

In the meta-analysis for the outcome disability, based on three trials (Andrade 2008; Lankhorst 1983; Meng 2009), there was very low-quality evidence (downgraded due to risk of bias, inconsistency, and publication bias) at short-term follow-up that Back School was slightly better than no treatment (MD –3.38, 95% CI –6.70 to –0.05; I^2 = 0%). At intermediate-term follow-up, based on three trials (Andrade 2008; Lankhorst 1983; Lønn 1999), there was very low-quality evidence (downgraded due to imprecision, risk of bias, and publication bias) that Back School was no better than no treatment (MD –5.92, 95% CI –12.08 to 0.23; I^2 = 0%). At long-term follow-up, based on two trials (Lankhorst 1983; Lønn 1999), there was very low-quality evidence (downgraded due to imprecision, risk of bias, and publication bias) that there was no important difference between Back School and no treatment (MD -7.36, 95% CI -22.05 to 7.34; I^2 = 76%) (Analysis 1.2).

None of the included studies reported adverse events or work status.

Comparison 2: Back School versus medical care

Five trials evaluated the effectiveness of Back School compared to medical care for chronic LBP (Berwick 1989; Heymans 2006; Morone 2011; Ribeiro 2008; Tavafian 2007).

In the meta-analysis for the outcome pain, based on three trials (Berwick 1989; Morone 2011; Ribeiro 2008), there was very low-quality evidence (downgraded due to imprecision, risk of bias, and publication bias) that Back School reduces pain intensity compared with medical care at short-term follow-up (MD -10.16, 95% CI –19.11 to -1.22; I^2 = 62%). At intermediate-term follow-up, based on five trials (Berwick 1989; Heymans 2006; Morone 2011; Ribeiro 2008; Tavafian 2007), there was very low-quality evidence (downgraded due to risk of bias, inconsistency, and publication bias) that there was no important difference between Back School and medical care (MD -9.65, 95% CI -22.46 to 3.15; I^2 = 89%). Based on three trials (Berwick 1989; Heymans 2006; Morone 2011), there was very low-quality evidence (downgraded due to risk of bias, inconsistency, and publication bias) that Back School was no better than medical care at long-term follow-up (MD -5.71, 95% CI –20.27 to 8.84; I^2 = 87%) (Analysis 2.1).

For the outcome disability, based on two trials (Morone 2011; Ribeiro 2008), there was very low-quality evidence (downgraded due to imprecision, risk of bias, and publication bias) that Back School was no better than medical care at short-term follow-up (MD –1.19, 95% CI –7.02 to 4.64; I^2 = 0%). At intermediate-term follow-up, three trials provided very low-quality evidence (downgraded due to imprecision, risk of bias, and publication bias) that Back School was better than medical care (MD –6.34, 95% CI –10.89 to –1.79; I^2 = 0%) (Heymans 2006; Morone 2011; Ribeiro 2008). At long-term follow-up, one trial, Heymans 2006, provided inconclusive evidence that Back School improves disability compared with medical care (MD –0.40, 95% CI –7.33 to 6.53; I^2 = not applicable) (very low quality evidence; downgraded due to imprecision, risk of bias and publication bias) (Analysis 2.2).

Only one study (Heymans 2006) measured adverse effects and reported that two workers in the Back School group (n=98), reported a strong increase in low back pain. However, the result reported means without standard deviations or did not report group size; we were therefore unable to statistically pool the data. None of the included studies reported work status.

Comparison 3: Back School versus passive physiotherapy

Four trials evaluated the effectiveness of Back School compared to passive physiotherapy for chronic LBP (Cecchi 2010a; Jaromi 2012; Lankhorst 1983; Postacchini 1988). One trial did not report any usable information (Postacchini 1988).

In the meta-analysis for the outcome pain, based on three trials (Cecchi 2010a; Jaromi 2012; Lankhorst 1983), there was very low-quality evidence (downgraded due to imprecision, risk of bias, inconsistency, and publication bias) that Back School is no better than passive physiotherapy at short-term follow-up (MD 1.96, 95% CI –9.51 to 13.43; I^2 = 94%). Based on three trials (Cecchi 2010a; Jaromi 2012; Lankhorst 1983), it is uncertain that there is any difference between back school and passive physiotherapy at intermediate term (MD -16.89, 95% CI -66.56 to 32.79; I^2 = 100%) and long-term follow-up (MD -12.86, 95% CI –61.22 to 35.50; I^2 = 100%)(very low quality evidence; downgraded due to imprecision, risk of bias, inconsistency, and publication bias) (Analysis 3.1).

In the meta-analysis for the outcome disability, based on two trials (Cecchi 2010a; Lankhorst 1983), there was very low-quality evidence (downgraded due to imprecision, risk of bias, inconsistency, and publication bias) that Back School was no better than passive physiotherapy (MD 2.57, 95% CI –15.88 to 21.01; I^2 = 82%) at short-term follow-up. At intermediate-term follow-up, two trials provided very low-quality evidence (downgraded due to imprecision, risk of bias, and publication bias) that there was no important difference between Back School and passive physiotherapy (MD 6.88, 95% CI -4.86 to 18.63; I^2 = 74%) (Cecchi 2010a; Lankhorst 1983). At long-term follow-up, two trials, Cecchi 2010a and Lankhorst 1983, provided very low-quality evidence (downgraded due to imprecision, risk of bias, and publication bias) that passive physiotherapy was better than Back School (MD 9.60, 95% CI 3.65 to 15.54; I^2 = 23%) (Analysis 3.2).

None of the included studies reported adverse events or work status.

Comparison 4: Back School versus exercise

Eight trials evaluated the effectiveness of Back School compared to exercise for chronic LBP (Costantino 2014; Devasahayam 2014; Donzelli 2006; Dufour 2010; Durmus 2014; Garcia 2013; Klaber Moffett 1986; Penttinen 2002).

In the meta-analysis for the outcome pain, based on five trials (Devasahayam 2014; Donzelli 2006; Durmus 2014; Garcia

2013; Klaber Moffett 1986), there was very low-quality evidence (downgraded due to risk of bias, inconsistency, and publication bias) that Back School is no better than exercise at short-term follow-up (MD -2.06, 95% CI –14.58 to 10.45; I^2 = 84%). There was low-quality evidence (downgraded due to inconsistency and publication bias) that there was no important difference between Back School and exercise at intermediate-term follow-up (MD -4.46, 95% CI –19.44 to 10.52; I^2 = 94%) based on four trials (Dufour 2010; Durmus 2014; Garcia 2013; Klaber Moffett 1986). At long-term follow-up, three trials provided low-quality evidence (downgraded due to inconsistency and publication bias) that exercise was no better than Back School in reducing pain (MD 4.58, 95% CI –0.20 to 9.36; I^2 = 0%) (Analysis 4.1) (Donzelli 2006; Dufour 2010; Garcia 2013).

In the meta-analysis for the outcome disability, there was very low-quality evidence (downgraded due to risk of bias, inconsistency, and publication bias) that there was no important difference between Back School and exercise at short-term follow-up (MD -1.65, 95% CI –8.66 to 5.37; I^2 = 85%) based on six trials (Costantino 2014; Devasahayam 2014; Donzelli 2006; Durmus 2014; Garcia 2013; Klaber Moffett 1986). At intermediate-term follow-up, six trials provided very low-quality evidence (downgraded due to risk of bias, inconsistency, and publication bias) that Back School was no better than exercise (MD 1.57, 95% CI –3.86 to 7.00; I^2 = 88%) (Costantino 2014; Devasahayam 2014; Dufour 2010; Garcia 2013; Klaber Moffett 1986; Penttinen 2002). Based on four trials (Donzelli 2006; Dufour 2010; Garcia 2013; Penttinen 2002), there was very low-quality evidence (downgraded due to risk of bias, inconsistency, and publication bias) that there was no significant difference between Back School and exercise at long-term follow-up (MD 4.54, 95% CI -4.44 to 13.52; I^2 = 80%) (Analysis 4.2).

Two studies (Dufour 2010; Garcia 2013) measured adverse effects. One participant in the Back School group reported a temporary exacerbation of pain (Garcia 2013) and 5 patients in exercise group experienced worsening of leg pain (Dufour 2010). However, the results reported means without standard deviations or did not report group size; we were therefore unable to statistically pool the data. None of the included studies reported work status.

Discussion

Summary of main results

It is uncertain if Back School is effective for chronic non-specific LBP, as we only located very low- to low-quality evidence. The pooled effect sizes were typically small and/or not statistically significant.

Overall completeness and applicability of evidence

Based on the low number of available studies and limited comparison treatments, the overall evidence is incomplete and the comparative effectiveness of Back School versus other contemporary treatments for chronic LBP is unknown. The Back School interventions varied from intensive (36 sessions during 12 weeks in Dufour 2010) to non-intensive (4 sessions during 4 weeks in Garcia 2013). This difference in treatment programmes could affect the generalisability of the evidence. Most included trials did not provide information about the care provider, hindering the generalisability of our findings to other settings.

Quality of the evidence

Based on the GRADE approach, the quality of the evidence varied from very low to low, the main problems being inconsistency, risk of bias, and publication bias. The most commonly identified methodological deficiencies were lack of blinding of participants and care providers (scored as high risk of bias in all 30 RCTs); lack of blinding of assessors (scored as high risk of bias or unclear in 18 RCTs); inappropriate method of randomisation (scored as high risk of bias or unclear in 18 RCTs); inadequate concealment of treatment allocation (scored as high risk of bias or unclear in 18 RCTs); and selective reporting (scored as high risk of bias or unclear in 23 RCTs). It is very difficult to blind this type of treatment, and because of the use of self reported outcomes (at least in terms of pain and disability), very difficult to blind the assessor.

Potential biases in the review process

In this systematic review, we aimed to perform a meta-analysis for some comparisons to provide quantitative estimates of treatment effects. However, some of the trials did not report sufficient information (e.g. means, standard deviations, or group size), which prevented us from providing a quantitative summary of the data from these trials. Furthermore, a limited number of studies reported return-to-work outcomes and adverse effects. Due to this lack of information, we were unable to statistically pool the data and consequently performed a best-evidence synthesis. Of particular note was the heterogeneity among studies for the content of Back School and type of control interventions. Due to a high statistical heterogeneity of some comparisons, we used a random-effects model to perform the meta-analysis. An additional limitation was that for most comparisons it was not possible to search for evidence of publication bias using funnel plots as too few studies were included.

Agreements and disagreements with other studies or reviews

In general, the results of this review are reasonably consistent with the previous Cochrane review regarding pain and disability outcomes (Heymans 2004). In the current review, Back School was minimally more effective than no treatment for pain and disability outcomes at short term, but not at intermediate- or long-term follow-up. This result is consistent with that from the previous review, which found conflicting evidence on the effectiveness of Back School compared to waiting-list controls or placebo interventions for all outcomes.

The previous review found moderate evidence that Back School is more effective than other treatments for the outcomes pain and functional status at short- and intermediate-term follow-ups, but not at long-term follow-up. In this review, we

stratified ‘other treatments’ into medical care, passive physiotherapy, and exercise because we considered these treatments to be sufficiently different that they should be evaluated separately. For all of these control treatments, our results were inconsistent or we did not find any significant differences in effectiveness when compared to Back School for pain and disability outcomes for all time periods.

Authors' conclusions

Implications for practice

We found only low- or very low-quality evidence for all comparisons, outcomes, and follow-up periods investigated. Regardless of the comparison treatment used (as well as the outcomes investigated), the results of the meta-analysis showed no difference or a trivial effect in favour of Back School. There does not seem to be sufficient justification for using Back School in clinical practice.

Implications for research

Given the scarcity and low quality of evidence in this area, a large, well-designed randomised controlled trial is very likely to change our conclusions on the effectiveness of Back School for chronic non-specific low back pain. However, Back School is not endorsed by guidelines. Further research into this area may not be necessary.

Acknowledgements

Patricia Parreira is supported by CAPES (Coordenação de Aperfeiçoamento de Pessoal de Nível Superior), Brazil. Chris Maher is supported by National Health and Medical Research Council of Australia.

Contributions of authors

- Final approval of the protocol: all authors
- Collection and assembly of data: Patricia Parreira, Bart W Koes, and Nolwenn Poquet
- Analysis and interpretation of the data: Patricia Parreira, Martijn W Heymans, Maurits van Tulder, Rosmin Esmail, Bart W Koes, Chung-Wei Christine Lin, Nolwenn Poquet, and Chris G Maher
- Drafting of the article: Patricia Parreira, Nolwenn Poquet, and Chris G Maher
- Final approval of the article: all authors

Declarations of interest

PP, MH, RE, BK, NP, CL have no conflicts of interest.

Two review authors (CM and MvT) are on the Editorial Board of the Cochrane Back and Neck Review Group. Editors are required to conduct at least one Cochrane review, which ensures that they are aware of the processes and commitment needed to conduct reviews.

Differences between protocol and review

In 2015 we published a new protocol for this review.

We stratified ‘other treatments’ into medical care, passive physiotherapy, and exercise because we considered these treatments to be sufficiently different that they should be evaluated separately. We classified the intensity of the interventions and clarified how adverse events would be measured. We planned a sensitivity analysis using different cut-off points, i.e. high quality defined as either five or seven of the 11 items scored positive. However, during the execution of the review, we were guided by the Cochrane group to examine all studies on five types of biases and not the 11 internal validity criteria. Based on that, it was impracticable run the sensitivity analyses. We updated the methods to be in line with the Furlan 2015 method guidelines.

Published notes

Characteristics of studies

Characteristics of included studies

Andrade 2008

Methods	RCT
Participants	57 participants. 1. Back School group n = 29. 2. Waiting-list group n = 28. Inclusion criteria: non-specific chronic low back pain for over 3 months, pain present during the study, and cognitive ability to sign the consent form. Exclusion criteria: pregnancy, disc herniation, infectious or inflammatory spondylitis, tumours, fractures, thoracic, shoulder, or neck pain, and fibromyalgia.
Interventions	1. Back School group: 4 sessions x 60 minutes in 4 weeks. Information on anatomy, causes of LBP, ergonomics, exercises, and advice on physical activity. 2. Waiting-list group.
Outcomes	1. Pain: visual analogue scale. 2. Disability: Roland-Morris Disability Questionnaire.
Notes	Secondary care setting. Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomised using a system developed in Visual Basic into 2 groups: experimental (34 participants) and control (36 participants).
Allocation concealment (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title, abstract, and flowchart indicate that it is an RCT.
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	Low risk	All participants were evaluated by the same examiner, who was blind to group allocation.
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%).
Intention-to-treat Analysis	Unclear risk	No information about intention-to-treat analysis
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes.
Similarity of baseline characteristics?	Low risk	Table I presents the data at baseline of the experimental and control groups, with no statistically significant difference between groups.
Co-interventions avoided or similar?	Unclear risk	Not mentioned
Compliance acceptable?	Low risk	Compliance was acceptable based on the reported intensity/dosage, duration, number, and frequency for both the intervention and control groups.
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time.

Berwick 1989

Methods	RCT
Participants	224 participants. 1. Back School group n = 72. 2. Usual care group n = 74. 3. Compliance Package n = 76. Inclusion criteria: low back pain, age 21 to 55 years, no serious comorbidity, no prior surgery, at least 2 weeks pain, maximum 6 months pain, no specific illness causing back pain, no prior episode during the previous year. Exclusion criteria: pain characteristically extended below the level of the knee.
Interventions	1. Back School group: a single 4-hour instruction session on LBP (psycho-educational). 2. Usual care group: participants were sent a single short pamphlet on LBP.
Outcomes	Pain: visual analogue scale.
Notes	Primary care setting. Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Allocation concealment (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	High risk	No mention of any attempts to blind the assessors
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%).
Intention-to-treat Analysis	Unclear risk	Not mentioned
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes.
Similarity of baseline characteristics?	Low risk	The only significant difference that randomisation failed to prevent was on Sickness Impact Profile
Co-interventions avoided or similar?	Low risk	Balanced for both groups
Compliance acceptable?	Unclear risk	Not mentioned
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time.

Cecchi 2010a

Methods	RCT
Participants	210 participants. 1. Back School n = 70. 2. Individual physiotherapy n = 70. 3. Spinal manipulation n = 70. Inclusion criteria: non-specific low back pain, reported "often" to "always" for at least the past 6 months. Exclusion criteria: neurological signs or symptoms, spondylolisthesis 4 second degree, rheumatoid arthritis or spondylitis, previous vertebral fractures, psychiatric disease, cognitive impairment, or pain-related litigation.
Interventions	1. Back School: 15 sessions x 1 hour for 3 weeks. The first 5 sessions were devoted to information and group discussions on back physiology and pathology, with reassurance on the benign character of common low back pain and education in ergonomics at home and in different occupational settings by slides and demonstrations. The next 10 sessions included relaxation techniques, postural and respiratory group exercises, and individually tailored back exercises. Each Back School group included 8 participants. *All participants received a booklet with evidence-based, standardised educational information on basic back anatomy and biomechanics, optimal postures, ergonomics, and advice to stay active. 2. Individual physiotherapy: 15 sessions x 60 minutes for 3 weeks. Included passive and assisted mobilisation, active exercise, massage/treatment of the soft tissues, and proprioceptive neuromuscular facilitation, with emphasis on patient education and active treatment. 3. Spinal manipulation: 4 to 6 sessions (as needed) x 20 minutes for 4 to 6 weeks. Spinal manipulation given according to Manual Medicine.
Outcomes	1. Pain: Pain Rating Scale. 2. Disability: Roland-Morris Disability Questionnaire.
Notes	Setting not specified. Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Simple (non-restricted) randomisation led to some imbalances in participants' baseline characteristics.
Allocation concealment (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned.
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	Low risk	The examiners were blinded to group assignment.
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%).
Intention-to-treat Analysis	High risk	Analysis was substantially similar to the intention-to-treat analysis commonly adopted in reporting randomised trials due to the minimal dropout (5/210, 2.4%).
Selective reporting (reporting bias)	Low risk	It was clear that the published report includes all expected outcomes.
Similarity of baseline characteristics?	Low risk	No significant difference across the groups was found.
Co-interventions avoided or similar?	Low risk	Balanced for both groups
Compliance acceptable?	Unclear risk	There are not enough data.
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time.

Costantino 2014

Methods	RCT
Participants	54 participants. 1. Back School group n = 27. 2. Hydrotherapy group n = 27. Inclusion criteria: participants aged between 65 and 80 years; diagnosis of chronic non-specific low back pain. Exclusion criteria: presence of musculoskeletal disorders, severe heart failure, or internal medicine pathologies that could interfere with moderate physical activity; fever or infectious disease; systemic inflammatory or rheumatologic diseases; previous spinal surgery or a history of vertebral traumas/fractures; instrumental physical therapies or physiotherapeutic therapies in the previous 3 months.
Interventions	1. Back School group: In the first session, individuals were informed about the anatomy of the spinal column, its functioning and ergonomic position and the basis of the pain-inducing mechanism, psychological aspects and stress management, whereas in the following sessions they performed stretching and muscular strengthening, associated with proper breathing. 2. Hydrotherapy group: Participants at first performed walking exercises to adapt to the pool conditions, and afterwards performed bilateral stretching and selective muscle strengthening exercises.
Outcomes	1. Disability: Roland-Morris Disability Questionnaire.
Notes	Setting not specified. Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The participants were randomly allocated using computer randomisation software (RANDI2 software version 0.6.1) to the Back School programme (group A) or to the hydrotherapy programme (group B).
Allocation concealment (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	High risk	No mention of any attempts to blind the assessors
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%).
Intention-to-treat Analysis	Low risk	All analyses were performed based on the intention-to-treat principle.
Selective reporting (reporting bias)	Low risk	It was clear that the published report included all expected outcomes.
Similarity of baseline characteristics?	Low risk	No significant difference across the groups was found.
Co-interventions avoided or similar?	Low risk	Balanced for both groups
Compliance acceptable?	Low risk	Compliance was acceptable based on the reported intensity/dosage, duration, number, and frequency for both the intervention and control groups.
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time.

Dalichau 1999

Methods	RCT
Participants	120 participants. 1. Back School group n = 60. 2. Waiting-list control group n = 60. Inclusion criteria: chronic, recurrent low back pain, age 20 to 40 years, no use of treatment because of acute back pain, no Back School experience, working full time, no expectation of an occupational disease at the time of enrolment.
Interventions	1. Back School group: 6 sessions (6 to 8 different modules) of 90 minutes in 8 weeks including education (anatomy, pathology, ergonomic, optimal posture during work and other activities) and exercises (isometric and dynamic strength, stretching and relaxation exercises, work simulating). 2. Waiting-list control group.
Outcomes	Pain: Pain Rating Scale.
Notes	Occupational setting. Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Allocation concealment (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	High risk	No mention of any attempts to blind the assessors
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%).
Intention-to-treat Analysis	Unclear risk	Not mentioned
Selective reporting (reporting bias)	Unclear risk	Not mentioned
Similarity of baseline characteristics?	Low risk	Demographic baseline characteristics of the study population are presented in Table 1.
Co-interventions avoided or similar?	Unclear risk	Not mentioned
Compliance acceptable?	Unclear risk	Not mentioned
Timing outcome assessments similar?	Unclear risk	Not mentioned

Devasahayam 2014

Methods	RCT
Participants	28 participants. 1. Back School group n = 14. 2. Mat-based exercises group n = 14. Inclusion criteria: Candidates with non-specific low back pain with a pain score < 8 on the verbal numerical pain (VNP) scale, and without significantly impaired spinal mobility, were included in this study. Only candidates who could read and speak English were included. Exclusion criteria: Candidates suffering from numbness, paraesthesia, or radicular symptoms were excluded from this study, as were those with any other musculoskeletal disorders of the lower limbs or upper- and mid-back pain. Candidates with red flags such as cancer, fractures, inflammatory or infective diseases, other neurological disorders, and those having spinal surgery less than 6 months prior to the study were also excluded.
Interventions	1. Back School group: The participants in the experimental group performed functional back exercises and had back care instruction amounting to 1-hour duration for each session. The participants received training in specific tasks like lifting, sitting, or mopping in order to correct their body mechanics in their ADL. The first 15 minutes of the session was a PowerPoint presentation on correct postures like upright sitting and standing postures, proper body mechanics of ADL like lifting, mopping and sweeping, walking, going up and down the stairs, information on ergonomic correction and activity pacing. This was followed by a functional task practice of all the above-mentioned ADL for the next 30 minutes. 2. Mat-based exercises group: The participants in the control group performed generic mat-based exercises commonly used to treat people with chronic low back pain. These exercises were not focused on any specific body mechanics or postures. The stretches were performed in reclined position on an exercise mat for the quadriceps, hamstrings, calf, hip external rotators, and spine (such as cat/dog stretches and prayer stretches). Mat exercises (e.g. knee hugs, knee rocking, lumbar rotation, and pelvic tilts in the supine position), mat-based core stability exercises were also performed. 2 sets of 10 repetitions of each exercise were performed for the 1-hour duration of each session; this was continued for 4 consecutive sessions once a week. The participants were instructed to follow the exercises as performed by the physiotherapist. The sessions were kept less interactive than they would be in a regular group exercise class.
Outcomes	1. Pain: numerical pain scale. 2. Disability: Roland-Morris Disability Questionnaire.
Notes	Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Allocation concealment (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Blinding of participants and personnel (performance bias)	High risk	Due to the nature of the interventions, it was not possible to blind the participants.
Blinding (performance bias and detection bias)	High risk	Due to the nature of the interventions, it was not possible to blind the therapists.
Blinding of outcome assessment (detection bias)	Low risk	An independent investigator collected data before and after the exercise classes.
Incomplete outcome data (attrition bias)	High risk	Only 15 participants completed the study; 13 participants dropped out of the study due to non-compliance or inability to obtain time-off from work, or both.
Intention-to-treat Analysis	Unclear risk	Not mentioned
Selective reporting (reporting bias)	Unclear risk	Not mentioned
Similarity of baseline characteristics?	Low risk	No significant difference across the groups was found.
Co-interventions avoided or similar?	Low risk	Balanced for both groups
Compliance acceptable?	High risk	Only 15 participants completed the study; 13 participants dropped out of the study due to non-compliance or inability to obtain time-off from work, or both.
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time.

Donchin 1990

Methods	RCT
Participants	138 participants. 1. Back School group n = 46. 2. Calisthenics exercises group n = 46. 3. Waiting-list control group n = 46. Inclusion criteria: at least 3 annual episodes of low back pain. Exclusion criteria: not described.
Interventions	1. Back School group: 4, 90-minute sessions during a 2-week period plus a 5th session after 2 months. Each group of 10 to 12 participants was supervised by a physiotherapist (education and exercises for back and abdominal muscles). 2. Calisthenics exercises group: 45-minute sessions biweekly for 3 months in groups of 10 to 12 participants (flexion and pelvic tilt exercises in order to strengthen the abdominal muscles, expanding spinal forward flexion). 3. Waiting-list control group.
Outcomes	Disability: Oswestry Low Back Pain Questionnaire.
Notes	Occupational setting. Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	After being examined, the participants were allocated to the 3 groups by a systematic random sampling method.
Allocation concealment (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	High risk	No mention of any attempts to blind the assessors
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%).
Intention-to-treat Analysis	Unclear risk	Not mentioned
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes.
Similarity of baseline characteristics?	Low risk	Demographic and clinical baseline characteristics of the study population are presented in Table 1. Demographic and clinical baseline characteristics were similar for both groups.
Co-interventions avoided or similar?	Unclear risk	There were few reported co-interventions in the study.
Compliance acceptable?	Low risk	Based on the description of both groups, compliance was acceptable.
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time.

Donzelli 2006

Methods	quasi-RCT
Participants	43 participants. 1. Back School group n = 22. 2. Pilates group n = 21. Inclusion criteria: chronic LBP without peripheral irradiation for at least 3 months; neurological values within the normal range; negative Lasegue's test and Wassermann test. Exclusion criteria: clinical history of spinal surgery; neurological values outside the normal range; radicular pain with positive Lasegue's and Wassermann's signs and straight leg raise test; structural deformities such as spondylolisthesis; stenosis of the vertebral canal; computed tomography or nuclear magnetic resonance documented disc hernia; rheumatoid arthritis or other rheumatologically related pathologies; conditions unrelated to the spinal column that mimic lumbalgic symptoms.
Interventions	1. Back School group: 10 sessions/60 minutes. During each session, participants performed all the exercises listed in the protocol. The protocol included postural education exercises, respiratory education, muscular extension and strengthening exercises of the paravertebral muscles and lower limbs, mobilising exercises for the spinal column and antalgic postures. During each treatment session, the therapist taught the participants some theoretical notions of the anatomy and pathology of the spinal column and in the principles of postural education. 2. Pilates group: 10 sessions/60 minutes. The protocol comprised a programme of exercise modules that made it easier to adapt the exercise to the requirements of each participant in each group. The protocol comprised postural education, stretching exercises, and breathing education.
Outcomes	1. Pain: visual analogue scale. 2. Disability: Roland-Morris Disability Questionnaire.
Notes	Secondary care setting. Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Used a quasi-random procedure
Allocation concealment (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	High risk	No mention of any attempts to blind the assessors
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%).
Intention-to-treat Analysis	Unclear risk	Not mentioned
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes.
Similarity of baseline characteristics?	Low risk	Demographic and clinical baseline characteristics were similar for both groups.
Co-interventions avoided or similar?	Unclear risk	There were few reported co-interventions in the study.
Compliance acceptable?	Low risk	Compliance was acceptable based on the descriptions of both groups.
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time.

Dufour 2010

Methods	RCT
Participants	272 participants. 1. Back School group n = 129. 2. Muscle training exercises group n = 143. Inclusion criteria: low back pain lasting more than 12 weeks with or without pain radiating into the leg(s), and aged 18 to 60 years. Exclusion criteria: symptoms of serious spinal pathology such as malignancy, osteoporosis, vertebral fracture, spinal stenosis, clinical symptoms of an acute herniated disc accompanied by nerve root entrapment, unstable spondylolisthesis, spondylitis, health conditions that prevented them from performing strenuous exercise, and language problems.
Interventions	1. Back School group: 36 sessions x 2 hours for 12 weeks. Participants received a programme of combined exercise, education, and pain management based on a programme described by Bendix. At the first session, a pre-programme assessment was performed to familiarise participants with the exercise programme, set treatment goals, and set the initial intensity for each exercise. The bulk of the session consisted of aerobic training and training to strengthen the muscles in the back, gluteus region, and abdominal wall. These exercises were all performed in the supine position using machines and circuit training. A total of 22 hours of exercises was performed. In addition, participants were provided 1.5 hours to play ball games, 1.5 hours of training in hot water, and 2 hours of ball stick training. Bi-weekly lessons on anatomy, postural techniques, and pain management were provided by a physiotherapist and on back care and lifting techniques by an occupational therapist, for a total of 10 hours. During the second period, 2-hour exercise sessions were performed twice a week at the study site and once a week at the participant's home. During the third period, 2-hour exercise sessions were performed 3 times a week at home. The participants performed a total of 75 hours of moderate muscle training exercise. The treatment-related cost per participant amounted to 12 hours of therapist assistance. 2. Muscle training exercises group: 24 sessions x 1 hour for 12 weeks. Participants received a programme of specific and intensive muscle training exercises to strengthen and shorten the muscles in the back and gluteus region. The programme did not include stretching or abdominal muscle exercises.
Outcomes	1. Pain: visual analogue scale. 2. Disability: Roland-Morris Disability Questionnaire. 3. Adverse events: reported by the physiotherapists on standardised forms.
Notes	Secondary care setting. Funding: The Danish National Board of Health.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were allocated by a separate secretary to a group-based multidisciplinary biopsychosocial rehabilitation programme (group A) or intensive individually therapist-assisted back muscle strengthening exercises (group B) according to a random number chart made for each subgroup provided by the Copenhagen Trial Unit, Center for Clinical Intervention Research, Rigshospitalet.
Allocation concealment (selection bias)	Low risk	Participants were allocated by a separate secretary to a group-based multidisciplinary biopsychosocial rehabilitation programme (group A) or intensive individually therapist-assisted back muscle strengthening exercises (group B) according to a random number chart made for each subgroup provided by the Copenhagen Trial Unit, Center for Clinical Intervention Research, Rigshospitalet.
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	Low risk	All physical examinations at trial visits were performed by 1 physician who was blinded to the treatment group and had no access to the treatment area.
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%).
Intention-to-treat Analysis	Low risk	Data analysis was performed on the actual data on an intention-to-treat basis, with the last value carried forward.
Selective reporting (reporting bias)	Low risk	It was clear that the published report included all expected outcomes.
Similarity of baseline characteristics?	Low risk	Demographic and clinical baseline characteristics of the study population are presented in Table 1. There were no significant differences between the groups.
Co-interventions avoided or similar?	Unclear risk	Not mentioned
Compliance acceptable?	Unclear risk	There are insufficient data about the control group.
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time.

Durmus 2014

Methods	RCT
Participants	121 participants. 1. Back School group n = 61. 2. Exercise group n = 60. Inclusion criteria: people with low back pain for at least 3 months. Exclusion criteria: people with acute radicular signs or symptoms, those who had radiographic evidence of inflammatory disease affecting the spine, tumour; serious medical conditions for which exercise is contraindicated; history of spinal surgery; pregnancy.
Interventions	1. Back School group: 8 sessions within a 4-week period. Each session entailed approximately half an hour of didactic training and half an hour of practical training. The program was administered by a physiatrist. 2. Exercise group: The participants in both groups were treated with a group-exercise programme of 60 minutes of exercise 3 times a week.
Outcomes	1. Pain: visual analogue scale. 2. Disability: Oswestry Disability Index.
Notes	Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was allocated by numbered-envelopes method.
Allocation concealment (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	High risk	No mention of any attempts to blind the assessors
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%).
Intention-to-treat Analysis	Unclear risk	Not mentioned
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes.
Similarity of baseline characteristics?	Low risk	Demographic and clinical baseline characteristics of the study population are presented in Table 1. There were no significant differences between the groups.
Co-interventions avoided or similar?	Low risk	Balanced for both groups
Compliance acceptable?	Unclear risk	Not mentioned
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time.

Garcia 2013

Methods	RCT
Participants	148 participants. 1. Back School group n = 74. 2. McKenzie Method group n = 74. Inclusion criteria: Patients seeking care had to have non-specific low back pain of at least 3 months' duration and be between 18 and 80 years of age. Patients with any contraindication to physical exercise based on the recommendations of the guidelines of the American College of Sports Medicine. Exclusion criteria: Serious spinal pathology (e.g. tumours, fractures, inflammatory diseases), previous spinal surgery, nerve root compromise, cardiorespiratory illnesses, or pregnancy.
Interventions	1. Back School group: 4 sessions x 60 minutes for 4 weeks. Participants received theoretical and practical information during the treatment sessions. The first session was conducted individually, and the 3 remaining sessions were conducted in groups. 2. McKenzie Method: 4 sessions x 60 minutes for 4 weeks. Participants received theoretical information regarding the care of the spine and performed specific exercises according to the direction of preference of movement according to the McKenzie Method.
Outcomes	1. Pain: numerical pain scale. 2. Disability: Roland-Morris Disability Questionnaire. 3. Adverse events: reported by the physiotherapists on standardised forms.
Notes	Primary care setting. Funding: Fundação de Amparo a Pesquisa do Estado de São Paulo (FAPESP).

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A simple randomisation sequence was computer generated using Microsoft Excel (Microsoft Corporation, Redmond, Washington) by one of the investigators of the study who was not directly involved with the assessment and treatment of participants.
Allocation concealment (selection bias)	Low risk	The allocation was concealed by using consecutively numbered, sealed, opaque envelopes.
Blinding of participants and personnel (performance bias)	High risk	Given the nature of the interventions, it was not possible to blind the therapist or participants.
Blinding (performance bias and detection bias)	High risk	Given the nature of the interventions, it was not possible to blind the therapist or participants.
Blinding of outcome assessment (detection bias)	Low risk	This study was a prospectively registered, 2-arm randomised controlled trial with a blinded assessor.
Incomplete outcome data (attrition bias)	Low risk	146 (98.6%) of participants completed the follow-up at 1 month for the primary outcome measures of pain and disability and for the secondary outcome measure of quality of life.
Intention-to-treat Analysis	Low risk	The statistical analysis was conducted on an intention-to-treat basis.
Selective reporting (reporting bias)	Low risk	It was clear that the published report included all expected outcomes.
Similarity of baseline characteristics?	Low risk	Groups did not differ in the baseline characteristics.
Co-interventions avoided or similar?	Low risk	Balanced for both groups
Compliance acceptable?	Low risk	Based on the descriptions of both groups, compliance was acceptable.
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time.

Heymans 2006

Methods	RCT
Participants	299 participants. 1. Back School (low-intensity) group n = 98. 2. Back School (high-intensity) group n = 98. 3. Usual care group n = 103. Inclusion criteria: workers; non-specific low back pain; being sick-listed (completely or partially) between 3 and 6 weeks; age 18 to 65 years; and ability to complete written questionnaires in the Dutch language. Exclusion criteria: sick-listed due to low back pain less than 1 month before the onset of the current episode of sick-leave; specific pathology; pregnancy.
Interventions	1. Back School (low-intensity) group: 4 sessions x 120 minutes for 4 weeks. 2. Back School (high-intensity) group: 16 sessions x 60 minutes for 8 weeks. 3. Usual care group: Participants allocated to this group received usual care provided by the occupational physician according to the Dutch guidelines for the occupational health management of patients with low back pain. After 12 weeks of continued sick-leave, the occupational physician was advised to refer the worker to more intensive interventions such as Back Schools or a multidisciplinary rehabilitation programme.
Outcomes	1. Pain: visual analogue scale. 2. Disability: Roland-Morris Disability Questionnaire. 3. Return to work: defined as the duration of work absenteeism in calendar days from the first day of sick-leave until full return to own work or other work with equal earnings for at least 4 weeks without (partial or full) dropout. 4. Adverse events: reported by the physiotherapists on standardised forms.
Notes	Secondary care setting. Funding: The Netherlands Organisation for Health Research and Development (ZonMw), Dutch Ministries of Health, Welfare and Sports and of Social Affairs and Employment.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Using sealed, opaque envelopes, coded according to a computerised random number generator, participants were randomly allocated to either the low-intensity Back School, high-intensity Back School, or usual care group.
Allocation concealment (selection bias)	Low risk	Using sealed, opaque envelopes, coded according to a computerised random number generator, participants were randomly allocated to either the low-intensity Back School, high-intensity Back School, or usual care group.
Blinding of participants and personnel (performance bias)	High risk	Occupational and family physicians and physiotherapists were not blinded for the allocated intervention.
Blinding (performance bias and detection bias)	High risk	Occupational and family physicians and physiotherapists were not blinded for the allocated intervention.
Blinding of outcome assessment (detection bias)	Low risk	An independent research assistant extracted the work absence data.
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%).
Intention-to-treat Analysis	Low risk	"Applying the intention-to-treat (ITT) principle, we included all patients in the analysis according to the group determined at randomisation."
Selective reporting (reporting bias)	Low risk	It was clear that the published report included all expected outcomes.
Similarity of baseline characteristics?	Low risk	Participants did not differ in baseline characteristics.
Co-interventions avoided or similar?	Unclear risk	Not mentioned
Compliance acceptable?	Low risk	Compliance was acceptable based on the reported intensity/dosage, duration, number, and frequency for both the intervention and control groups.
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time.

Hurri 1989

Methods	RCT
Participants	188 participants. 1. Back School group n = 95. 2. Instruction material of the Back School in written form group n = 93. Inclusion criteria: idiopathic LBP for at least 12 months, LBP present on at least 1 day each week during the preceding month, and/or ADL limitations. Exclusion criteria: rheumatoid arthritis or other connective tissue disease as well as people with a history of back surgery.
Interventions	1. Back School group: modified Swedish Back School: 60-minute education and exercise sessions, 6 times in 3 weeks. Refresher course 2 x 60 minutes after 6 months. Supervised by physiotherapist; 11 participants per group. 2. Instruction material of the Back School in written form group: No actual treatment, but free to use healthcare services.
Outcomes	1. Pain: visual analogue scale. 2. Disability: Oswestry Disability Index.
Notes	Occupational setting. Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The participants were randomly assigned to one of two groups.
Allocation concealment (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	High risk	No mention of any attempts to blind the assessors
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%).
Intention-to-treat Analysis	Unclear risk	Not mentioned
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes.
Similarity of baseline characteristics?	Low risk	The 2 groups were comparable for age and duration of low back pain syndrome.
Co-interventions avoided or similar?	Low risk	Balanced for both groups
Compliance acceptable?	Low risk	Compliance was acceptable based on the reported intensity/dosage, duration, number, and frequency for both the intervention and control groups.
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time.

Jaromi 2012

Methods	RCT
Participants	111 participants. 1. Back School group n = 56. 2. Passive physiotherapy group n = 55. Inclusion criteria: nurses working in the inpatient department of the university clinics, having LBP syndrome in their medical history, under 60 years of age; more than 3 months of lower back pain with or without referred pain; and having a current active diagnosis of chronic LBP. Exclusion criteria: pregnancy; previous spinal surgery; current nerve root entrapment accompanied by significant neurological deficit; spinal cord compression; tumours; severe structural deformity; severe instability; severe osteoporosis; inflammatory disease of the spine; spinal infection; severe cardiovascular or metabolic disease; depression; and connective tissue disorder.
Interventions	1. Back School group: 6 sessions for 6 weeks. Sessions of ergonomics training and Back School once a week for a duration of 6 weeks. Each therapy session was divided into a 10-minute ergonomics training exercise, a 20-minute muscle strengthening and stretching exercise. 2. Passive physiotherapy group: 1 session for 6 weeks of transcutaneous electrical nerve stimulation (TENS) therapy and heat therapy, which participants were advised to practise at home daily.
Outcomes	1. Pain: numerical pain scale.
Notes	Occupational setting. Funding: The Netherlands Organisation for Health Research and Development (ZonMw), Dutch Ministries of Health, Welfare and Sports and of Social Affairs and Employment.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Nurses having chronic LBP syndrome were randomised into 2 groups to receive either ergonomics training and Back School (education) or passive therapy.
Allocation concealment (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title, abstract, and flowchart indicate that it is an RCT.
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	Low risk	The examiner was kept blinded.
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%).
Intention-to-treat Analysis	Unclear risk	No information about intention-to-treat analysis
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes.
Similarity of baseline characteristics?	Low risk	Based on Table 1, participants did not differ in baseline characteristics.
Co-interventions avoided or similar?	Low risk	Balanced for both groups
Compliance acceptable?	Unclear risk	There are insufficient data about the control group.
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time.

Keijsers 1989

Methods	RCT
Participants	40 participants. 1. Back School treatment group n = 20. 2. Waiting-list control group n = 20. Inclusion criteria: low back pain for at least 6 months. Exclusion criteria: medical contraindication list which specified medical disorders and diseases.
Interventions	1. Back School treatment group: Maastricht Back School: education and skills program in group setting (10 to 12 participants per group), 7 lessons of 2.5 hours and refresher lesson after 8 weeks. Included postural education, exercises, information on psychological factors. 2. Waiting-list control group.
Outcomes	1. Pain: visual analogue scale.
Notes	Setting not specified. Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned.
Allocation concealment (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Blinding of participants and personnel (performance bias)	Unclear risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	High risk	No mention of any attempts to blind the assessors
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%).
Intention-to-treat Analysis	Unclear risk	Not mentioned
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes.
Similarity of baseline characteristics?	Unclear risk	Not mentioned
Co-interventions avoided or similar?	Unclear risk	There were few reported co-interventions in the study.
Compliance acceptable?	Unclear risk	There are insufficient data about the control group.
Timing outcome assessments similar?	Unclear risk	Not mentioned

Keijsers 1990

Methods	RCT
Participants	90 participants. 1. Back School treatment group n = 45. 2. Waiting-list control group n = 45. Inclusion criteria: LBP for at least 2 months and maximum of 3 years. Exclusion criteria: people eligible for surgical treatment were excluded, as were those who were unable to participate in a physical exercise program and relaxation training.
Interventions	1. Back School group: Maastricht Back School, education and skills program in group setting (10 to 12 participants per group), 7 lessons of 2.5 hours and refresher lesson after 6 months. Included postural education, exercises, information on psychological factors. 2. Waiting-list control group.
Outcomes	1. Pain: visual analogue scale. 2. Return to work was expressed in number of days.
Notes	Primary care setting. Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Allocation concealment (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	High risk	No mention of any attempts to blind the assessors
Incomplete outcome data (attrition bias)	High risk	Dropouts exceed 20%.
Intention-to-treat Analysis	Unclear risk	Not mentioned
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes.
Similarity of baseline characteristics?	Unclear risk	Not mentioned
Co-interventions avoided or similar?	Unclear risk	Not mentioned
Compliance acceptable?	Unclear risk	Not mentioned
Timing outcome assessments similar?	Unclear risk	Not mentioned

Klaber Moffett 1986

Methods	RCT
Participants	78 participants. 1. Back School treatment group n = 40. 2. Exercises group n = 38. Inclusion criteria: chronic (6 months or more) LBP with or without lower limb pain. Exclusion criteria: history of spinal surgery; person concurrently attending physiotherapy treatment; and evidence of underlying disease, such as fracture, ankylosing spondylitis, or multiple myeloma.
Interventions	1. Back School treatment group: Swedish Back School, 3 sessions containing education on anatomy and body mechanics, semi-Fowler position, ergonomic counselling, and exercises aimed at strengthening the abdominal muscles. 2. Exercises group.
Outcomes	1. Pain: visual analogue scale. 2. Disability: Oswestry Low Back Pain Questionnaire.
Notes	Primary care setting. Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The participants were randomly allocated to 2 groups and were assessed by a rheumatologist who was not aware of treatment allocated.
Allocation concealment (selection bias)	Low risk	The participants were randomly allocated to 2 groups and were assessed by a rheumatologist who was not aware of treatment allocated.
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	High risk	No mention of any attempts to blind the assessors
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%).
Intention-to-treat Analysis	Unclear risk	Not mentioned
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes.
Similarity of baseline characteristics?	Low risk	Based on Table 1, participants did not differ in baseline characteristics.
Co-interventions avoided or similar?	Unclear risk	There were few reported co-interventions in the study.
Compliance acceptable?	Low risk	Compliance was acceptable based on the reported intensity/dosage, duration, number, and frequency for both the intervention and control group.
Timing outcome assessments similar?	Unclear risk	Not mentioned

Lankhorst 1983

Methods	RCT
Participants	43 participants. 1. Back School treatment group n = 21. 2. Electrotherapy n = 22. Inclusion criteria: idiopathic LBP of more than 6 months duration, not responding to conventional physiotherapy. Exclusion criteria: inflammatory or other specific disorders of the spine such as ankylosing spondylitis, abnormal reflexes, sensory loss, or muscle weakness.
Interventions	1. Back School treatment group: Swedish Back School: 4 sessions of 45 minutes each over the course of 2 weeks (anatomy and causes of LBP, function muscles and posture, ergonomics, advice on physical activity). 2. Electrotherapy: 4 sessions with detuned short-wave diathermy in a period of 2 weeks.
Outcomes	1. Pain: mean pain score (on 10-point scale).
Notes	Setting not specified. Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Allocation concealment (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	High risk	No mention of any attempts to blind the assessors
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%).
Intention-to-treat Analysis	Unclear risk	Not mentioned
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes.
Similarity of baseline characteristics?	Low risk	Based on Table 1, participants did not differ in baseline characteristics.
Co-interventions avoided or similar?	Unclear risk	Not mentioned
Compliance acceptable?	Unclear risk	There are insufficient data about the control group.
Timing outcome assessments similar?	Unclear risk	Not mentioned

Lønn 1999

Methods	RCT
Participants	81 participants. 1. Active Back School group n = 43. 2. No-treatment group n = 38. Inclusion criteria: individuals of both genders, 18 to 50 years of age, at least 1 episode of low back pain in the last year, and finished treatment and sick leave at the time of enrolment. Exclusion criteria: previous surgical procedures for LBP, pregnancy. specific rheumatologic diseases, spondylolisthesis, spinal tumour, spinal fracture, drug or alcohol abuse, and documented mental illness.
Interventions	1. Active Back School group: 20 sessions of 1 hour each over 13 weeks, consisting of education (anatomy, biomechanics, pathology, ergonomic principles) and exercise (ergonomic, functional, strength and stretching exercises of upper body, pelvis, and leg muscles and joints, simulation of home and work activities). 2. No-treatment group.
Outcomes	1. Pain: overall experienced pain.
Notes	Mixed study setting. Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT
Allocation concealment (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	High risk	No mention of any attempts to blind the assessors
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%).
Intention-to-treat Analysis	Unclear risk	Not mentioned
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes
Similarity of baseline characteristics?	Low risk	Based on Table 1, participants did not differ in baseline characteristics
Co-interventions avoided or similar?	Low risk	Balanced for both groups
Compliance acceptable?	Low risk	Compliance was acceptable based on the reported intensity/dosage, duration, number, and frequency for both the intervention and control groups
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time

Meng 2009

Methods	RCT
Participants	360 participants. 1. Back School group n = 187. 2. Usual care group n = 173. Inclusion criteria: people with chronic LBP.
Interventions	1. Back School group: 7 sessions x 60 minutes. 2. Usual care group: 7 sessions x 60 minutes.
Outcomes	1. Pain: numerical pain scale.
Notes	Secondary care setting. Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Allocation concealment (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	High risk	No mention of any attempts to blind the assessors
Incomplete outcome data (attrition bias)	High risk	Dropouts exceeded 20%
Intention-to-treat Analysis	Unclear risk	Not mentioned
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes.
Similarity of baseline characteristics?	Unclear risk	Not mentioned
Co-interventions avoided or similar?	Low risk	Balanced for both groups
Compliance acceptable?	Unclear risk	There are insufficient data about the control group
Timing outcome assessments similar?	Unclear risk	Not mentioned

Morone 2011

Methods	RCT
Participants	62 participants. 1. Back School group n = 41. 2. Usual care group n = 21. Inclusion criteria: age between 18 and 80 years, chronic non-specific low back pain persisting for at least 3 months. Exclusion criteria: acute low back pain; pain due to a specific cause (e.g. fracture, spondylolisthesis, disc herniation, and lumbar stenosis); scheduled back surgery; severe cognitive impairments; pregnancy; and the presence of concomitant rheumatological, neurological, psychiatric, cardiological, respiratory, or oncological diseases that could affect spine function or alter the perception of pain.
Interventions	1. Back School group: 10 sessions x 60 minutes for 4 weeks. 2. Usual care group: same medical and pharmacological assistance as the other group.
Outcomes	1. Pain: visual analogue scale. 2. Disability: Oswestry Disability Index. 3. Disability: Waddell Disability Index.
Notes	Mixed study setting. Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title, abstract, and flowchart indicate that it is an RCT
Allocation concealment (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title, abstract, and flowchart indicate that it is an RCT
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	Unclear risk	The study is described as a single-blind RCT, but there is not enough information to determine who was blinded
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%)
Intention-to-treat Analysis	Unclear risk	No information about intention-to-treat analysis
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes
Similarity of baseline characteristics?	Low risk	Participants did not differ in baseline characteristics
Co-interventions avoided or similar?	Unclear risk	Not mentioned
Compliance acceptable?	Low risk	Compliance was acceptable based on the reported intensity/dosage, duration, number, and frequency for both the intervention and control groups
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time

Morone 2012

Methods	RCT
Participants	75 participants. 1. Back School group n = 25. 2. Perceptive rehabilitation group n = 25. 3. Control group n = 25. Inclusion criteria: people aged 18 to 75 years with chronic non-specific low back pain persisting for at least 3 months. Exclusion criteria: acute pain, LBP due to specific cause (fracture, spondylolisthesis, disc herniation, and lumbar stenosis), presence of rheumatological, neurological or oncological concomitant disease, back surgery before study, cognitive impairment (Mini-Mental State Examination score < 24), and pregnancy.
Interventions	1. Back School group: 10 sessions for 4 weeks. Information on anatomy, causes of LBP, ergonomics, exercises, and advice on physical activity. 2. Perceptive rehabilitation group: 20 sessions x 45 minutes for 4 weeks 3. Control group: same medical and pharmacological assistance as the other groups.
Outcomes	1. Pain: visual analogue scale. 2. Pain: McGill Pain Questionnaire. 3. Disability: Oswestry Disability Index. 4. Disability: Waddell Disability index.
Notes	Secondary care setting. Funding: this research received no specific grant from any commercial or public funding agency.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title, abstract, and flowchart indicate that it is an RCT
Allocation concealment (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title, abstract, and flowchart indicate that it is an RCT
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	High risk	The study is described as a single-blind RCT, but there is not enough information to determine who was blinded
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%)
Intention-to-treat Analysis	Unclear risk	No information about intention-to-treat analysis
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes
Similarity of baseline characteristics?	Low risk	Based on Table 1, participants did not differ in baseline characteristics
Co-interventions avoided or similar?	Low risk	Balanced for both groups
Compliance acceptable?	Low risk	Compliance was acceptable based on the reported intensity/dosage, duration, number, and frequency for both the intervention and control groups
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time

Nentwig 1990

Methods	RCT
Participants	74 participants. 1. Back School group n = 32. 2. Waiting-list group n = 42. Inclusion criteria: degenerative LBP (on a waiting list for a Back School). Exclusion criteria: acute pain, LBP due to specific cause (fracture, spondylolisthesis, disc herniation, and lumbar stenosis), presence of rheumatological, neurological, or oncological concomitant disease, back surgery before study, cognitive impairment (Mini-Mental State Examination score < 24), and pregnancy.
Interventions	1. Back School group: 4 sessions x 2 hours for 4 weeks. 2. Waiting list.
Outcomes	1. Pain (own instrument).
Notes	Setting not specified. Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Allocation concealment (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	High risk	No mention of any attempts to blind the assessors
Incomplete outcome data (attrition bias)	Unclear risk	Not mentioned
Intention-to-treat Analysis	Low risk	Not mentioned
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes.
Similarity of baseline characteristics?	Unclear risk	Not mentioned
Co-interventions avoided or similar?	Unclear risk	Not mentioned
Compliance acceptable?	Low risk	Compliance was acceptable based on the reported intensity/dosage, duration, number, and frequency for both the intervention and control groups.
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time.

Paolucci 2012b

Methods	RCT
Participants	50 participants. 1. Back School group n = 29. 2. Medical-assistance group n = 21. Inclusion criteria: age between 18 and 80 years and a diagnosis of chronic non-specific low back pain.
Interventions	1. Back School group: 10 sessions over 4 weeks. First theoretical lesson and then treated 3 times per week for 3 weeks. All sessions lasted 1 hour. Each group included 4 or 5 participants. First session carried out by physicians: education about general anatomical information related to spine, its functioning, and ergonomic positions in daily living, pain concepts, psychological aspects, stress management, workplace situation, and sport activities. 9 sessions carried out by physiotherapist: exercises based on the re-education of breathing, self stretching trunk muscles, erector spine reinforcement, abdominal reinforcement, and postural exercises. Ergonomic use of the spine in daily life with self correction and how to cope with spine stressing positions during work were explained. 2. Medical assistance.
Outcomes	1. Pain: visual analogue scale. 2. Dsability: Oswestry Disability Index.
Notes	Secondary care setting. Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The concealed randomisation was performed by means of sealed envelopes
Allocation concealment (selection bias)	Low risk	The concealed randomisation was performed by means of sealed envelopes
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	High risk	No mention of any attempts to blind the assessors
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%)
Intention-to-treat Analysis	Unclear risk	Not mentioned
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes
Similarity of baseline characteristics?	Low risk	Based on Table 1, participants did not differ in baseline characteristics
Co-interventions avoided or similar?	Unclear risk	Not mentioned
Compliance acceptable?	Low risk	Compliance was acceptable based on the descriptions of both groups
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time

Paolucci 2012a

Methods	RCT
Participants	30 participants. 1. Back School group n = 15. 2. Perceptive rehabilitation group n = 15. Inclusion criteria: a diagnosis of chronic non-specific low back pain and age between 18 and 75 years.
Interventions	1. Back School group: 10 sessions x 45 minutes for 4 weeks. Comprised an initial lesson on theory and 3 practical sessions per week for 3 weeks. 2. Perceptive rehabilitation group: Utilised a specific tool called "surface for perceptive rehabilitation" composed of about 100 deformable latex cones with a small top, fixed to a rigid surface. Perceptive rehabilitation is a therapeutic system based on the interaction between the patient's body trunk and a support surface.
Outcomes	1. Pain: McGill Pain Questionnaire.
Notes	Secondary care setting. Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title, abstract, and flowchart indicate that it is an RCT.
Allocation concealment (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title, abstract, and flowchart indicate that it is an RCT.
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	High risk	No mention of any attempts to blind the assessors
Incomplete outcome data (attrition bias)	Unclear risk	Not mentioned
Intention-to-treat Analysis	Unclear risk	No mentioned
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes.
Similarity of baseline characteristics?	Unclear risk	Not mentioned
Co-interventions avoided or similar?	Unclear risk	Not mentioned
Compliance acceptable?	Unclear risk	There are insufficient data about the control group.
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time.

Penttinen 2002

Methods	RCT
Participants	93 participants. 1. Back School group n = 47. 2. Fitness training n = 46. Inclusion criteria: age between 35 and 50 years, non-specific back pain (excluded if an exact diagnosis was present), gradual development of back pain lasting at least 1 month at the time of selection, no medical problems preventing physical training, and full consent to participate in the Back School. Exclusion criteria: not described.
Interventions	1. Back School group: 21 sessions (8 supervised and 13 voluntary group meetings) of 85 minutes each over 10 weeks. Swedish type of Back School including fitness training (muscle force, endurance, and stretching exercises for upper and lower back, trunk flexors, upper arm and leg muscles, and ergonomic work techniques), group discussions (structure, functioning and strain of the back, lifting, principles of physical exercises during leisure time and at work), and extra meetings consisting of physical training and social intercourse. 2. Fitness training: 10 sessions of 1 hour each over 5 weeks.
Outcomes	1. Disability: Oswestry Disability Questionnaire.
Notes	Occupational setting. Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Allocation concealment (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	High risk	No mention of any attempts to blind the assessors
Incomplete outcome data (attrition bias)	High risk	Dropouts exceeded 20%.
Intention-to-treat Analysis	Unclear risk	Not mentioned
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes.
Similarity of baseline characteristics?	Low risk	Based on Table 1, participants did not differ in baseline characteristics.
Co-interventions avoided or similar?	Unclear risk	There were few reported co-interventions in the study.
Compliance acceptable?	Unclear risk	There are insufficient data about the control group.
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time.

Postacchini 1988

Methods	RCT
Participants	240 participants. 1. Back School treatment group n = 50. 2. Spinal manipulation by chiropractor group n = 52. 3. Usual care n = 47. 4. Physiotherapy group n = 91. Inclusion criteria: continuous or almost continuous back pain lasting more than 2 months; episode of acute pain on a chronic history of pain. Exclusion criteria: LBP related to neoplastic diseases of the spine; pregnant or nursing women; people with serious general diseases.
Interventions	1. Back School treatment group: based on Canadian Back Education Unit: 4, 1-hour sessions in a 1-week period (including muscle exercises). 2. Spinal manipulation by chiropractor: daily for the first week and then twice a week for 6 weeks. 3. Usual care: drug therapy, non-steroidal anti-inflammatory drugs (15 to 20 days). 4. Physiotherapy: physiotherapy, light massage, analgesic currents and diathermy daily for 3 weeks.
Outcomes	1. Pain: visual analogue scale.
Notes	Secondary care setting. Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Allocation concealment (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title and abstract indicate that it is an RCT.
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	High risk	No mention of any attempts to blind the assessors
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%).
Intention-to-treat Analysis	Unclear risk	Not mentioned
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes.
Similarity of baseline characteristics?	Unclear risk	Not mentioned
Co-interventions avoided or similar?	Unclear risk	Not mentioned
Compliance acceptable?	Unclear risk	There are insufficient data about the control group.
Timing outcome assessments similar?	Unclear risk	Not mentioned

Ribeiro 2008

Methods	RCT
Participants	55 participants. 1. Back School group n = 26. 2. Medical assistance n = 29. Inclusion criteria: aged 18 to 65 years diagnosed with chronic non-specific low back pain with mechanical characteristics lasting more than 3 months. Exclusion criteria: previous back surgery, spinal tumour, spinal fracture, pregnancy, fibromyalgia, inflammatory or infectious spinal diseases, and litigant patients.
Interventions	1. Back School group: 3 sessions during 2 months. Orientation was given regarding the anatomy and physiology of the spine, causes and treatment of low back pain, and ergonomic guidelines relevant to back problems. Abdominal and back strengthening exercises were also performed. 2. Medical assistance.
Outcomes	1. Pain: visual analogue scale. 2. Disability: Roland-Morris Disability Questionnaire.
Notes	Secondary care setting. Funding: 2 authors (DCR and DA) received support from the University of Otago (University of Otago Doctoral Scholarship).

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Folded pieces of paper indicating 1 of the groups were placed in sealed envelopes which were placed in a container. Another investigator selected the envelopes to determine to which group individual participants would belong.
Allocation concealment (selection bias)	Low risk	Folded pieces of paper indicating 1 of the groups were placed in sealed envelopes which were placed in a container. Another investigator selected the envelopes to determine to which group individual participants would belong.
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	Low risk	Participants were assessed by an investigator (physiotherapist) blinded to treatment groups.
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%).
Intention-to-treat Analysis	High risk	Participants who failed to complete all 4 assessments were also considered dropouts and were excluded from the statistical analysis.
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes.
Similarity of baseline characteristics?	Low risk	Based on Table 1, participants did not differ in baseline characteristics.
Co-interventions avoided or similar?	Unclear risk	Not mentioned
Compliance acceptable?	Low risk	Compliance was acceptable based on the reported intensity/dosage, duration, number, and frequency for both the intervention and control groups.
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time.

Sahin 2011

Methods	RCT
Participants	146 participants. 1. Back School group n = 73. 2. Exercise group n = 73. Inclusion criteria: non-specific low back pain for longer than 12 weeks without neurological deficits. Exclusion criteria: people who had continuous pain, age ≤ 18 years, those who had already attended the Back School programme, those who had previously undergone surgery, who had structural anomalies, spinal cord compressions, severe instabilities, severe osteoporosis, acute infections, severe cardiovascular or metabolic diseases, who were pregnant, and those with a body mass index above 30 kg/m^2.
Interventions	1. Back School group: 4 sessions x 60 minutes for 2 weeks, participants received exercise, physical treatment modalities, and a Back School programme. 2. Exercise group: received exercise and physical treatment modalities.
Outcomes	1. Pain: visual analogue scale. 2. Disability: Oswestry Disability Index.
Notes	Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Concealed randomisation was conducted using sealed, opaque envelopes coded according to a computerised random number generator.
Allocation concealment (selection bias)	Low risk	Concealed randomisation was conducted using sealed, opaque envelopes coded according to a computerised random number generator.
Blinding of participants and personnel (performance bias)	High risk	No mention of any attempts to blind the participants
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	Low risk	All participants were examined by the same physician, who was blind to the type of therapy.
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%).
Intention-to-treat Analysis	Unclear risk	Not mentioned
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes.
Similarity of baseline characteristics?	Low risk	Based on Table 1, participants did not differ in baseline characteristics.
Co-interventions avoided or similar?	Low risk	Balanced for both groups
Compliance acceptable?	Low risk	Compliance was acceptable based on the reported intensity/dosage, duration, number, and frequency for both the intervention and control groups.
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time.

Tavafian 2007

Methods	RCT
Participants	102 participants. 1. Back School group n = 50. 2. Medical assistance n = 52. Inclusion criteria: age 18 years and over, suffering from chronic back pain (persisting for 90 days or more), and having a telephone number for regular contact with a responsible caregiver. Exclusion criteria: back surgery within the 2 years prior to the initial observation, or if the complaint was restricted to the sacroiliac joint or the cervical or thoracic regions, or if there was congenital spine disease. People with a low back complaint that had persisted less than 90 days were also excluded.
Interventions	1. Back School group: 5 sessions for 4 days. Multidimensional and interdisciplinary educational regimen designed to assess each patient's physical condition, personal characteristics, lifestyle, and subsequent ability to cope. The program utilises an empowerment approach, providing a combination of knowledge, skills, and heightened self awareness regarding values and needs, so that patients can define and achieve their own goals. 2. Medical assistance: only medication.
Outcomes	1. Pain: subscale of 36-Item Short Form Health Survey (SF-36).
Notes	Secondary care setting. Funding: N/A.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The sequence generation procedure or the method of allocation were not mentioned. The title, abstract, and flowchart indicate that it is an RCT.
Allocation concealment (selection bias)	High risk	The treatment allocation was not concealed.
Blinding of participants and personnel (performance bias)	High risk	Participants were not blinded to the intervention.
Blinding (performance bias and detection bias)	High risk	No mention of any attempts to blind the care providers
Blinding of outcome assessment (detection bias)	High risk	No mention of any attempts to blind the assessors
Incomplete outcome data (attrition bias)	Low risk	The percentage of withdrawals and dropouts was within the acceptable rate (less than 20%).
Intention-to-treat Analysis	Low risk	The study used an intention-to-treat analysis.
Selective reporting (reporting bias)	Unclear risk	It was unclear if the published report included all expected outcomes.
Similarity of baseline characteristics?	Low risk	Participants did not differ in baseline characteristics.
Co-interventions avoided or similar?	Low risk	Co-interventions were avoided for both groups.
Compliance acceptable?	Low risk	Compliance was acceptable based on the descriptions of both groups.
Timing outcome assessments similar?	Low risk	All important outcomes assessments for both groups were measured at the same time.

Footnotes

ADL: activities of daily living
LBP: low back pain
N/A: not applicable
RCT: randomised controlled trial

Characteristics of excluded studies

Bergquist 1977

Reason for exclusion	The average time of symptoms in the inclusion criteria was characterised as acute LBP.

Cecchi 2010b

Reason for exclusion	Back School intervention consisted of education only, without exercises.

Demoulin 2006

Reason for exclusion	The intervention was not considered to be Back School.

Herzog 1991

Reason for exclusion	The average time of symptoms in the inclusion criteria was characterised as acute LBP.

Hsieh 2002

Reason for exclusion	The average time of symptoms in the inclusion criteria was characterised as acute LBP.

Härkäpää 1989

Reason for exclusion	Back School intervention consisted of education only, without exercises.

Härkäpää 1990

Reason for exclusion	Back School intervention consisted of education only, without exercises.

Indahl 1995

Reason for exclusion	The average time of symptoms in the inclusion criteria was characterised as acute LBP.

Indahl 1998

Reason for exclusion	Back School intervention consisted of education only, without exercises.

Leclaire 1996

Reason for exclusion	The average time of symptoms in the inclusion criteria was characterised as acute LBP.

Lindequist 1984

Reason for exclusion	The average time of symptoms in the inclusion criteria was characterised as acute LBP.

Linton 1989

Reason for exclusion	The intervention was not considered to be Back School.

Maul 2005

Reason for exclusion	Back School intervention consisted of education only, without exercises.

Mele 2006

Reason for exclusion	Back School intervention consisted of education only, without exercises.

Meng 2011

Reason for exclusion	The Back School intervention was not a clear contrast for the control group.

Morrison 1988

Reason for exclusion	Each group was assessed once, the control group at the beginning of the programme and the Back School group at the end.

Sadeghi-Abdollahi 2012

Reason for exclusion	The results are for a single group.

Tavafian 2008

Reason for exclusion	The intervention was not considered to be Back School.

Yang 2010

Reason for exclusion	The intervention was not considered to be Back School.

Footnotes

LBP: low back pain

Characteristics of studies awaiting classification

Garcia 2016

Methods	Randomised controlled trial
Participants	148 people with a diagnosis of chronic low back pain for at least 3 months.
Interventions	1. Back School group: 4 sessions x 60 minutes for 4 weeks. Participants allocated to this group received theoretical and practical information during the treatment sessions. The first session was conducted individually, and the 3 remaining sessions were conducted in groups. 2. McKenzie Method group: 4 sessions x 60 minutes for 4 weeks. Participants allocated to this group received theoretical information regarding the care of the spine and performed specific exercises according to the direction of preference of movement according to the McKenzie Method.
Outcomes	1. Pain: numerical pain scale. 2. Disability: Roland-Morris Disability Questionnaire. 3. Adverse events: reported by the physiotherapists on standardised forms.
Notes	

Paolucci 2016

Methods	Randomised controlled trial
Participants	53 people with a diagnosis of chronic low back pain for at least 3 months.
Interventions	1. Experimental group: Participants were treated in outpatient with a Back School programme. Each group consisted of 4 or 5 people who underwent the rehabilitation treatment twice a week for 5 consecutive weeks for a total of 10 sessions, each lasting about 1 hour. 2. Control group: Participants were treated in outpatient with the Feldenkrais Method. Each group consisted of 4 or 5 people who underwent the rehabilitation treatment twice a week for 5 consecutive weeks for a total of 10 sessions, each lasting about 1 hour.
Outcomes	1. Pain: visual analogue scale and McGill Pain Questionnaire. 2. Disability: Waddell Disability Index. 3. Quality of life: 36-Item Short Form Health Survey. 4. Mind-body interactions: Multidimensional Assessment of Interoceptive Awareness Questionnaire.
Notes	No funding was received in support of this work. Adverse events: not evaluated.

Footnotes

Characteristics of ongoing studies

IRCT201010184251N2

Study name	The effect of lumbar care (based on Back School) on nursing staff's low back pain and functional disability
Methods	Clinical trial, 2 arms, randomised controlled, single-blind
Participants	Individuals diagnosed with chronic low back pain. Inclusion criteria: nursing licence, work at hospital in the morning shift during the study, low back pain (based on self report). Exclusion criteria: does not follow the training, underwent back surgery within previous 2 years, congenital and inflammatory spine disease, pregnancy, severe osteoporosis (based on medical records).
Interventions	Intervention: a 3-hour lumbar care workshop based on Back School method. Control: routine care.
Outcomes	1. Functional disability: Roland-Morris Disability Questionnaire. 2. Pain: visual analogue scale.
Starting date	06 September 2015
Contact information	Name: Mehdi Pakbaz Address: Kodakyar Ave., Daneshjo Blvd., Evin, Post code: 1985713834, Tehran, Iran Email: ma.pakbaz@uswr.ac.ir; mehdi_pakbaz@live.com Affiliation: University of Social Welfare and Rehabilitation Sciences
Notes	

Footnotes

Summary of findings tables

1 Back School compared with no treatment for low back pain

Back School compared with no treatment for low back pain

Patient or population: people with low back pain

Intervention: Back School

Comparison: no treatment

Outcomes	Illustrative comparative risks (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)
	Assumed risk	Corresponding risk*			
	No treatment	Back School			
Pain: short-term follow-up (< 3 months) Multiple scales: scale from 0 to 100 (worse pain)	The mean pain at short-term follow-up ranged across control groups from 31.8 to 68 points.	The mean pain (short term) in the intervention groups was 6.10 lower (10.18 lower to 2.01 lower).	MD -6.10 (-10.18 to -2.01)	647 participants (6 studies)	⊕⊖⊖⊖ **very low**[2,3,4]
Pain: intermediate-term follow-up (3 to 6 months) Multiple scales: scale from 0 to 100 (worse pain)	The mean pain at intermediate-term follow-up ranged across control groups from 26 to 65 points.	The mean pain (intermediate term) in the intervention groups was 4.34 lower (14.37 lower to 5.68 higher).	MD -4.34 (-14.37 to 5.68)	257 participants (4 studies)	⊕⊖⊖⊖ **very low**[1,2,4]

Pain: long-term follow-up (> 6 months) Multiple scales: scale from 0 to 100 (worse pain)	The mean pain at long-term follow-up ranged across control groups from 38 to 58 points.	The mean pain (long term) in the intervention groups was 12.16 lower (29.14 lower to 4.83 higher).	MD -12.16 (-29.14 to 4.38)	244 participants (3 studies)	⊖⊖⊖⊖ **very low**[1,2,3,4]
Disability: short-term follow-up (< 3 months) Multiple scales: scale from 0 to 100 (worse disability)	The mean disability at short-term follow-up ranged across control groups from 29.3 to 60 points.	The mean disability (short term) in the intervention groups was 3.83 lower (6.70 lower to 0.05 lower).	MD -3.38 (-6.70 to -0.05)	426 participants (3 studies)	⊕⊖⊖⊖ **very low**[2,3,4]
Disability: intermediate-term follow-up (3 to 6 months) Multiple scales: scale from 0 to 100 (worse disability)	The mean disability at intermediate-term follow-up ranged across control groups from 39 to 53 points.	The mean disability (intermediate term) in the intervention groups was 5.92 lower (12.80 lower to 0.23 higher).	MD -5.92 (-12.08 to 0.23)	181 participants (3 studies)	⊕⊖⊖⊖ **very low**[1,2,4]
Disability: long-term follow-up (> 6 months) Multiple scales: scale from 0 to 100 (worse disability)	The mean disability long-term follow-up ranged across control groups from 48 to 51 points.	The mean disability (long term) in the intervention groups was 7.36 lower (22.05 lower to 7.34 higher).	MD -7.36 (-22.05 to 7.34)	124 participants (2 studies)	⊕⊖⊖⊖ **very low**[1,2,4]
Adverse events Not reported					
Work status Not reported					
The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). **CI:** confidence interval; **MD:** mean difference					
GRADE Working Group grades of evidence **High-quality evidence:** There are consistent findings among at least 75% of randomised controlled trials with low risk of bias; consistent, direct, and precise data; and no known or suspected publication biases. Further research is unlikely to change either the estimate or our confidence in the results. **Moderate-quality evidence:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. **Low-quality evidence:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. **Very low-quality evidence:** We are very uncertain about the results. **No evidence:** We identified no randomised controlled trials that addressed this outcome.					

Footnotes

[1]Downgraded one level due to imprecision (fewer than 400 participants in total).
[2]Downgraded one level due to risk of bias (> 25% of the participants were from studies with a high risk of bias).
[3]Downgraded one level due to clear inconsistency of results.
[4]Downgraded one level due to publication bias.

2 Back School compared with medical care for low back pain

Back School compared with medical care for low back pain					
Patient or population: people with low back pain **Intervention:** Back School **Comparison:** medical care					
	Illustrative comparative risks (95% CI)		**Relative effect (95% CI)**	**No of participants (studies)**	**Quality of the evidence (GRADE)**
	Assumed risk	**Corresponding risk***			
Outcomes	**Medical care**	**Back School**			

Pain: short-term follow-up (< 3 months) Multiple scales: scale from 0 to 100 (worse pain)	The mean pain at short-term follow-up ranged across control groups from 17 to 73 points.	The mean pain (short term) in the intervention groups was 10.16 lower (19.11 lower to 1.22 lower).	MD -10.16 (-19.11 to -1.22)	249 participants (3 studies)	⊕⊖⊖⊖ **very low**[1,2,4]
Pain: intermediate-term follow-up (3 to 6 months) Multiple scales: scale from 0 to 100 (worse pain)	The mean pain at intermediate-term follow-up ranged across control groups from 12 to 76 points.	The mean pain (intermediate term) in the intervention groups was 9.65 lower (22.46 lower to 3.15 higher).	MD -9.65 (-22.46 to 3.15)	545 participants (5 studies)	⊕⊖⊖⊖ **very low**[2,3,4]
Pain: long-term follow-up (> 6 months) Multiple scales: scale from 0 to 100 (worse pain)	The mean pain at long-term follow-up ranged across control groups from 12 to 65 points.	The mean pain (long term) in the intervention groups was 5.71 lower (20.27 lower to 8.84 higher).	MD -5.71 (-20.27 to 8.84)	406 participants (3 studies)	⊕⊖⊖⊖ **very low**[2,3,4]
Disability: short-term follow-up (< 3 months) Multiple scales: scale from 0 to 100 (worse disability)	The mean disability at short-term follow-up ranged across control groups from 24.8 to 41.2 points.	The mean disability at short-term follow-up in the intervention groups was 1.19 lower (7.02 lower to 4.64 higher).	MD -1.19 (-7.02 to 4.64)	130 participants (2 studies)	⊕⊖⊖⊖ **very low**[1,2,4]
Disability: intermediate-term follow-up (3 to 6 months) Multiple scales: scale from 0 to 100 (worse disability)	The mean disability at intermediate-term follow-up ranged across control groups from 25.8 to 43.3 points.	The mean disability at intermediate-term follow-up in the intervention groups was 6.34 lower (10.89 lower to 1.79 lower).	MD -6.34 (-10.89 to -1.79)	331 participants (3 studies)	⊕⊖⊖⊖ **very low**[1,2,4]
Disability: long-term follow-up (> 6 months) Multiple scales: scale from 0 to 100 (worse disability)	The mean disability at long-term follow-up was 32.9 points.	The mean disability at long-term follow-up in the intervention groups was 0.40 lower (7.33 lower to 6.53 higher).	MD -0.40 (-7.33 to 6.53)	201 participants (1 study)	⊕⊖⊖⊖ **very low**[1,2,4]
Adverse events Two workers in the Back School group (n=98) reported a strong increase in low back pain (Heymans 2006).					
Work status Not reported					
The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). **CI:** confidence interval; **MD:** mean difference					
GRADE Working Group grades of evidence **High-quality evidence:** There are consistent findings among at least 75% of randomised controlled trials with low risk of bias; consistent, direct, and precise data; and no known or suspected publication biases. Further research is unlikely to change either the estimate or our confidence in the results. **Moderate-quality evidence:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. **Low-quality evidence:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. **Very low-quality evidence:** We are very uncertain about the results. **No evidence:** We identified no randomised controlled trials that addressed this outcome.					

Footnotes

[1]Downgraded one level due to imprecision (fewer than 400 participants in total).
[2]Downgraded one level due to risk of bias (> 25% of the participants were from studies with a high risk of bias).
[3]Downgraded one level due to clear inconsistency of results.
[4]

Downgraded one level due to publication bias.

3 Back School compared with passive physiotherapy for low back pain

Back School compared with passive physiotherapy for low back pain

Patient or population: people with low back pain.

Intervention: Back School

Comparison: passive physiotherapy

Outcomes	Illustrative comparative risks (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)
	Assumed risk	Corresponding risk*			
	Passive physiotherapy	Back School			
pain: short-term follow-up (< 3 months) Multiple scales: scale from 0 to 100 (worse pain)	The mean pain at short-term follow-up ranged across control groups from 7.1 to 88 points.	The mean pain (short- term) in the intervention groups was 1.96 higher (9.51 lower to 13.43 higher).	MD 1.96 (-9.51 to 13.43)	290 participants (3 studies)	⊖⊖⊖⊖ **very low**[1,2,3,4]
pain - intermediate-term follow up (3-6 months) Multiple scales: scale from 0 to 100 (worse pain)	The mean pain at intermediate-term follow-up ranged across control groups from 13.3 to 65 points.	The mean pain (intermediate-term) in the intervention groups was 16.89 lower (66.56 lower to 32.79 higher).	MD -16.89 (-66.56 to 32.79)	290 participants (3 studies)	⊖⊖⊖⊖ **very low**[1,2,3,4]
pain - long-term follow-up (>6 months) Multiple scales: scale from 0 to 100 (worse pain)	The mean pain at long-term follow-up ranged across control groups from 11.6 to 60.5 points.	The mean pain (long- term) in the intervention groups was 12.86 lower (61.22 lower to 35.50 higher).	MD -12.86 (-61.22 to 35.50)	291 participants (3 studies)	⊖⊖⊖⊖ **very low**[1,2,3,4]
Disability - short-term follow-up (<3 months) Multiple scales: scale from 0 to 100 (worse disability)	The mean disability at short-term follow-up ranged across control groups from 9.1 to 60 points.	The mean disability at short-term follow-up in the intervention groups was 2.57 higher (15.88 lower to 21.01 higher).	MD 2.57 (-15.88 to 21.01)	180 participants (2 studies)	⊖⊖⊖⊖ **very low**[1,2,3,4]
Disability - intermediate-term follow up (3-6 months) Multiple scales: scale from 0 to 100 (worse disability)	The mean disability at intermediate-term follow-up ranged across control groups from 10.4 to 53 points.	The mean disability at short-term follow-up in the intervention groups was 6.88 higher (-4.86 lower to 18.63 higher).	MD 6.88 (-4.86 to 18.63).	180 participants (2 studies)	⊕⊖⊖⊖ **very low**[1,2,4]
Disability - long-term follow-up (>6 months) Multiple scales: scale from 0 to 100 (worse disability)	The mean disability at long-term follow-up ranged across control groups from 10.4 to 46 points.	The mean disability at long-term follow-up in the intervention groups was 9.60 higher (3.65 higher to 15.54 higher).	MD 9.60 (3.65 to 15.54)	180 participants (2 studies)	⊕⊖⊖⊖ **very low**[1,2,4]

Adverse events Not reported

Work status Not reported

The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; MD: mean difference

GRADE Working Group grades of evidence

High-quality evidence: There are consistent findings among at least 75% of randomised controlled trials with low risk of bias; consistent, direct, and precise data; and no known or suspected publication biases. Further research is unlikely to change either the estimate or our confidence in the results.

Moderate-quality evidence: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low-quality evidence: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low-quality evidence: We are very uncertain about the results.
No evidence: We identified no randomised controlled trials that addressed this outcome.

Footnotes

1 Downgraded one level due to imprecision (fewer than 400 participants, in total).
2 Downgraded one level due to risk of bias (> 25% of the participants were from studies with a high risk of bias).
3 Downgraded one level due to clear inconsistency of results.
4 Downgraded one level due to publication bias.

4 Back School compared with exercise for low back pain

Back School compared with exercise for low back pain

Patient or population: people with low back pain

Intervention: Back School

Comparison: exercise

Outcomes	Illustrative comparative risks (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)
	Assumed risk	Corresponding risk*			
	Exercise	Back School			
Pain: short-term follow-up (< 3 months) Multiple scales: scale from 0 to 100 (worse pain)	The mean pain at short-term follow-up ranged across control groups from 25 to 40 points.	The mean pain (short term) in the intervention groups was 2.06 lower (14.58 lower to 10.45 higher).	MD -2.06 (-14.58 to 10.45)	416 participants (5 studies)	⊕⊖⊖⊖ **very low**[2,3,4]
Pain: intermediate-term follow-up (3 to 6 months) Multiple scales: scale from 0 to 100 (worse pain)	The mean pain at intermediate-term follow-up ranged across control groups from 11.2 to 40 points.	The mean pain (intermediate term) in the intervention groups was 4.46 lower (19.44 lower to 10.52 higher).	MD -4.46 (-19.44 to 10.52)	619 participants (4 studies)	⊕⊕⊖⊖ **low**[3,4]
Pain: long-term follow-up (> 6 months) Multiple scales: scale from 0 to 100 (worse pain)	The mean pain at long-term follow-up ranged across control groups from 8.6 to 50.9 points.	The mean pain (long term) in the intervention groups was 4.58 higher (0.20 lower to 9.36 higher).	MD 4.58 (-0.20 to 9.36)	461 participants (3 studies)	⊕⊕⊖⊖ **low**[3,4]
Disability: short-term follow-up (< 3 months) Multiple scales: scale from 0 to 100 (worse disability)	The mean disability at short-term follow-up ranged across control groups from 4.5 to 29.1 points.	The mean disability at short-term follow-up in the intervention groups was 1.65 lower (8.66 lower to 5.37 higher).	MD -1.65 (-8.66 to 5.37)	471 participants (6 studies)	⊕⊖⊖⊖ **very low**[2,3,4]
Disability: intermediate-term follow-up (3 to 6 months) Multiple scales: scale from 0 to 100 (worse disability)	The mean disability at intermediate-term follow-up ranged across control groups from 2.87 to 29.5 points.	The mean disability at intermediate-term follow-up in the intervention groups was 1.57 higher (3.86 lower to 7.00 higher).	MD 1.57 (-3.86 to 7.00)	766 participants (6 studies)	⊕⊖⊖⊖ **very low**[2,3,4]

Disability: long-term follow-up (> 6 months) Multiple scales: scale from 0 to 100 (worse disability	The mean disability at long-term follow-up ranged across control groups from 3.3 to 28.3 points.	The mean disability at long-term follow-up in the intervention groups was 4.54 higher (4.44 lower to 13.52 higher).	MD 4.54 (-4.44 to 13.52)	556 participants (4 studies)	⊕⊖⊖⊖ **very low**[2,3,4]
Adverse events One participant in the Back School group reported a temporary exacerbation of pain (Garcia 2013) and 5 patients in exercise group experienced worsening of leg pain (Dufour 2010)					
Work status Not reported					
The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). **CI:** confidence interval; **MD:** mean difference					
GRADE Working Group grades of evidence **High-quality evidence:** There are consistent findings among at least 75% of randomised controlled trials with low risk of bias; consistent, direct, and precise data; and no known or suspected publication biases. Further research is unlikely to change either the estimate or our confidence in the results. **Moderate-quality evidence:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. **Low-quality evidence:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. **Very low-quality evidence:** We are very uncertain about the results. **No evidence:** We identified no randomised controlled trials that addressed this outcome.					

Footnotes

[1]Downgraded one level due to imprecision (fewer than 400 participants in total).
[2]Downgraded one level due to risk of bias (> 25% of the participants were from studies with a high risk of bias).
[3]Downgraded one level due to clear inconsistency of results.
[4]Downgraded one level due to publication bias.

Additional tables

1 Sources of risk of bias

Bias domain	Source of bias	Possible answers
Selection	(1) Was the method of randomization adequate?	Yes/no/unsure
Selection	(2) Was the treatment allocation concealed?	Yes/no/unsure
Performance	(3) Was the patient blinded to the intervention?	Yes/no/unsure
Performance	(4) Was the care provider blinded to the intervention?	Yes/no/unsure
Detection	(5) Was the outcome assessor blinded to the intervention?	Yes/no/unsure
Attrition	(6) Was the drop-out rate described and acceptable?	Yes/no/unsure
Attrition	(7) Were all randomized participants analyzed in the group to which they were allocated?	Yes/no/unsure
Reporting	(8) Are reports of the study free of suggestion of selective outcome reporting?	Yes/no/unsure
Selection	(9) Were the groups similar at baseline regarding the most important prognostic indicators?	Yes/no/unsure
Performance	(10) Were co-interventions avoided or similar?	Yes/no/unsure
Performance	(11) Was the compliance acceptable in all groups?	Yes/no/unsure
Detection	(12) Was the timing of the outcome assessment similar in all groups?	Yes/no/unsure
Other	(13) Are other sources of potential bias unlikely?	Yes/no/unsure

Footnotes

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2 Criteria for a judgment of "yes" for the sources of risk of bias

1	A random (unpredictable) assignment sequence. Examples of adequate methods are coin toss (for studies with 2 groups), rolling a dice (for studies with 2 or more groups), drawing of balls of different colours, drawing of ballots with the study group labels from a dark bag, computer-generated random sequence, preordered sealed envelopes, sequentially-ordered vials, telephone call to a central office, and preordered list of treatment assignments. Examples of inadequate methods are: alternation, birth date, social insurance/security number, date in which they are invited to participate in the study, and hospital registration number.
2	Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.
3	Index and control groups are indistinguishable for the patients or if the success of blinding was tested among the patients and it was successful.
4	Index and control groups are indistinguishable for the care providers or if the success of blinding was tested among the care providers and it was successful.
5	Adequacy of blinding should be assessed for each primary outcome separately. This item should be scored ‘‘yes’’ if the success of blinding was tested among the outcome assessors and it was successful or: • for patient-reported outcomes in which the patient is the outcome assessor (e.g., pain, disability): the blinding procedure is adequate for outcome assessors if participant blinding is scored ‘‘yes’’ • for outcome criteria assessed during scheduled visit and that supposes a contact between participants and outcome assessors (e.g., clinical examination): the blinding procedure is adequate if patients are blinded, and the treatment or adverse effects of the treatment cannot be noticed during clinical examination • for outcome criteria that do not suppose a contact with participants (e.g., radiography, magnetic resonance imaging): the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed when assessing the main outcome • 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, hospitalization length, treatment failure), in which the care provider is the outcome assessor: the blinding procedure is adequate for outcome assessors if item ‘‘4’’ (caregivers) is scored ‘‘yes’’ • for outcome criteria that are assessed from data of the medical forms: the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed on the extracted data
6	The number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 20% for short-term follow-up and 30% for long-term follow-up and does not lead to substantial bias a ‘‘yes’’ is scored. (N.B. these percentages are arbitrary, not supported by literature).
7	All randomized patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of noncompliance and co-interventions.
8	All the results from all prespecified outcomes have been adequately reported in the published report of the trial. This information is either obtained by comparing the protocol and the report, or in the absence of the protocol, assessing that the published report includes enough information to make this judgment.
9	Groups have to be similar at baseline regarding demographic factors, duration and severity of complaints, percentage of patients with neurological symptoms, and value of main outcome measure(s).
10	If there were no co-interventions or they were similar between the index and control groups.
11	The reviewer determines if the compliance with the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the index intervention and control intervention(s). For example, physiotherapy treatment is usually administered for several sessions; therefore it is necessary to assess how many sessions each patient attended. For single-session interventions (e.g., surgery), this item is irrelevant.
12	Timing of outcome assessment should be identical for all intervention groups and for all primary outcome measures.
13	Other types of biases. For example: • When the outcome measures were not valid. There should be evidence from a previous or present scientific study that the primary outcome can be considered valid in the context of the present. • Industry-sponsored trials. The conflict of interest (COI) statement should explicitly state that the researchers have had full possession of the trial process from planning to reporting without funders with potential COI having any possibility to interfere in the process. If, for example, the statistical analyses have been done by a funder with a potential COI, usually ‘‘unsure’’ is scored.

Footnotes

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Classification pending references

Data and analyses

1 Back School versus no treatment

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Pain	7		Mean Difference(IV, Random, 95% CI)	Subtotals only
1.1.1 short-term follow-up (<3 months)	6	647	Mean Difference(IV, Random, 95% CI)	-6.10 [-10.18, -2.01]
1.1.2 intermediate-term follow up (3-6 months)	4	257	Mean Difference(IV, Random, 95% CI)	-4.34 [-14.37, 5.68]
1.1.3 long-term follow-up (>6 months)	3	244	Mean Difference(IV, Random, 95% CI)	-12.16 [-29.14, 4.83]
1.2 Disability	4		Mean Difference(IV, Random, 95% CI)	Subtotals only
1.2.1 short-term follow-up (<3 months)	3	426	Mean Difference(IV, Random, 95% CI)	-3.38 [-6.70, -0.05]
1.2.2 intermediate-term follow up (3-6 months)	3	181	Mean Difference(IV, Random, 95% CI)	-5.92 [-12.08, 0.23]
1.2.3 long-term follow-up (>6 months)	2	124	Mean Difference(IV, Random, 95% CI)	-7.36 [-22.05, 7.34]

2 Back School versus medical care

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
2.1 Pain	5		Mean Difference(IV, Random, 95% CI)	Subtotals only
2.1.1 short-term follow-up (<3 months)	3	249	Mean Difference(IV, Random, 95% CI)	-10.16 [-19.11, -1.22]
2.1.2 intermediate-term follow up (3-6 months)	5	545	Mean Difference(IV, Random, 95% CI)	-9.65 [-22.46, 3.15]
2.1.3 long-term follow-up (>6 months)	3	406	Mean Difference(IV, Random, 95% CI)	-5.71 [-20.27, 8.84]
2.2 Disability	3		Mean Difference(IV, Random, 95% CI)	Subtotals only
2.2.1 short-term follow-up (<3 months)	2	130	Mean Difference(IV, Random, 95% CI)	-1.19 [-7.02, 4.64]
2.2.2 intermediate-term follow up (3-6 months)	3	331	Mean Difference(IV, Random, 95% CI)	-6.34 [-10.89, -1.79]
2.2.3 long-term follow-up (>6 months)	1	201	Mean Difference(IV, Random, 95% CI)	-0.40 [-7.33, 6.53]

3 Back School versus passive physiotherapy

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
3.1 Pain	3		Mean Difference(IV, Random, 95% CI)	Subtotals only
3.1.1 short-term follow-up (<3 months)	3	290	Mean Difference(IV, Random, 95% CI)	1.96 [-9.51, 13.43]
3.1.2 intermediate-term follow up (3-6 months)	3	290	Mean Difference(IV, Random, 95% CI)	-16.89 [-66.56, 32.79]
3.1.3 long-term follow-up (>6 months)	3	291	Mean Difference(IV, Random, 95% CI)	-12.86 [-61.22, 35.50]
3.2 Disability	2		Mean Difference(IV, Random, 95% CI)	Subtotals only
3.2.1 short-term follow-up (<3 months)	2	180	Mean Difference(IV, Random, 95% CI)	2.57 [-15.88, 21.01]
3.2.2 intermediate-term follow up (3-6 months)	2	180	Mean Difference(IV, Random, 95% CI)	6.88 [-4.86, 18.63]
3.2.3 long-term follow-up (>6 months)	2	180	Mean Difference(IV, Random, 95% CI)	9.60 [3.65, 15.54]

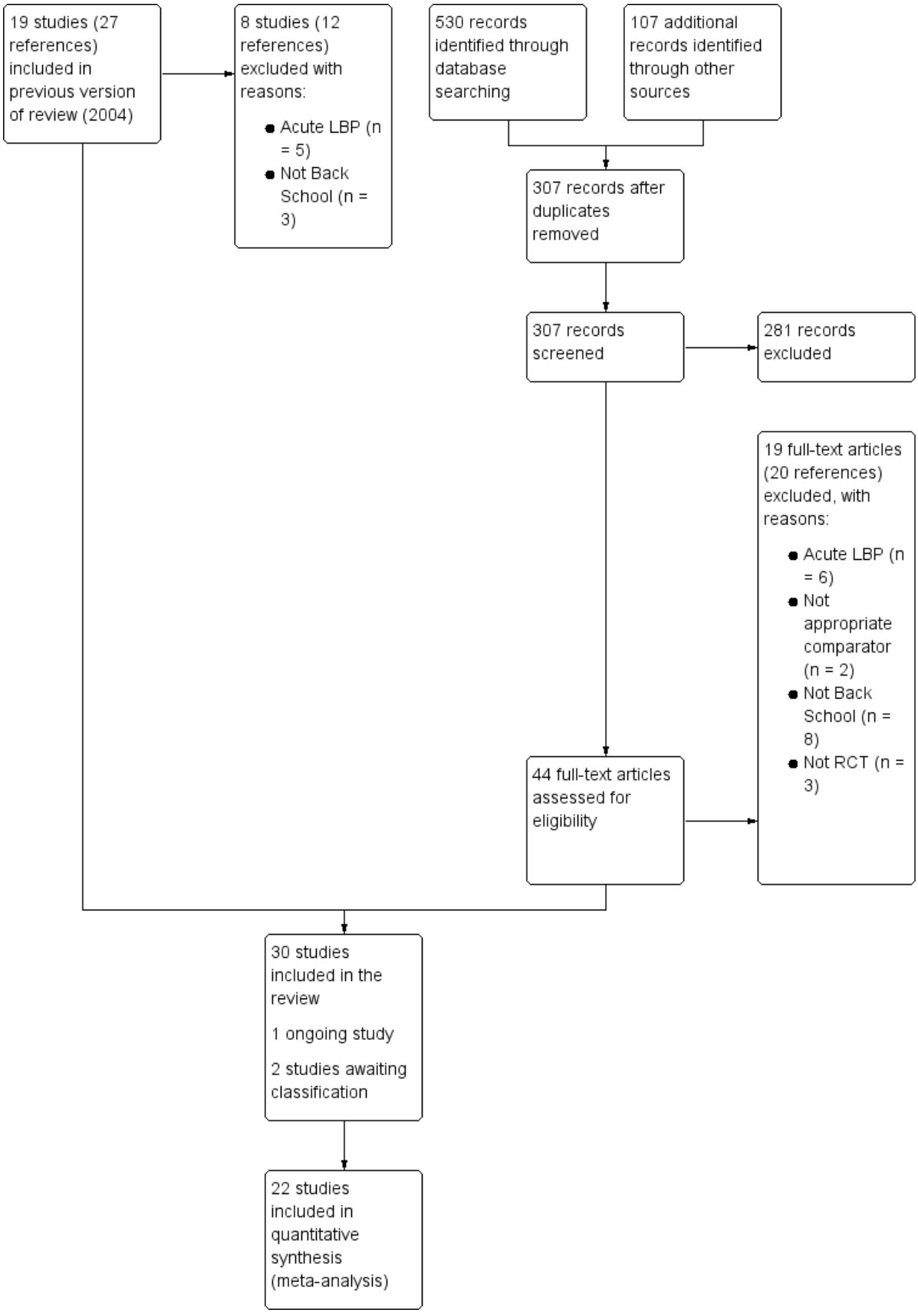
4 Back school versus exercise

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate

4.1 Pain	6		Mean Difference(IV, Random, 95% CI)	Subtotals only
4.1.1 short-term follow-up (<3 months)	5	416	Mean Difference(IV, Random, 95% CI)	-2.06 [-14.58, 10.45]
4.1.2 intermediate-term follow up (3-6 months)	4	619	Mean Difference(IV, Random, 95% CI)	-4.46 [-19.44, 10.52]
4.1.3 long-term follow-up (>6 months)	3	461	Mean Difference(IV, Random, 95% CI)	4.58 [-0.20, 9.36]
4.2 Disability	8		Mean Difference(IV, Random, 95% CI)	Subtotals only
4.2.1 short-term follow-up (<3 months)	6	471	Mean Difference(IV, Random, 95% CI)	-1.65 [-8.66, 5.37]
4.2.2 intermediate-term follow up (3-6 months)	6	766	Mean Difference(IV, Random, 95% CI)	1.57 [-3.86, 7.00]
4.2.3 long-term follow-up (>6 months)	4	556	Mean Difference(IV, Random, 95% CI)	4.54 [-4.44, 13.52]

Figures

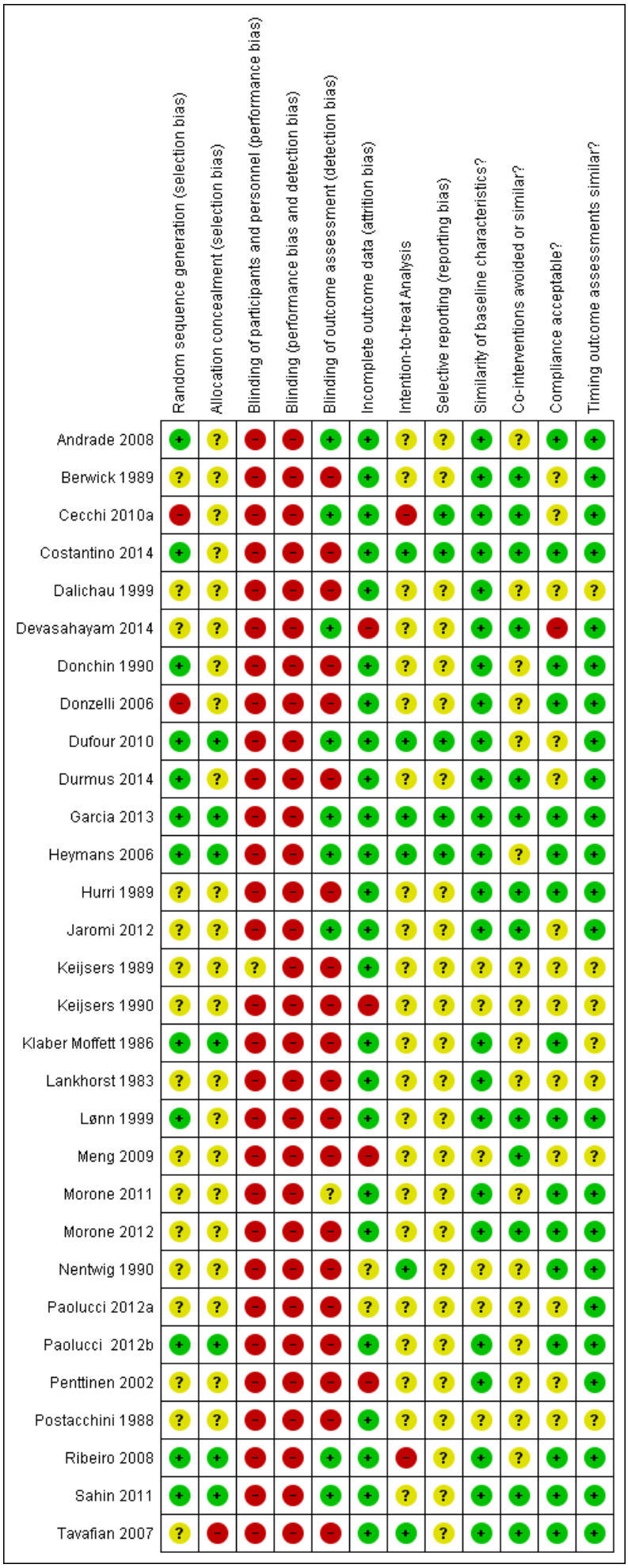
Figure 1



Caption

Study flow diagram.

Figure 2


Random sequence generation (selection bias)
Allocation concealment (selection bias)
Blinding of participants and personnel (performance bias)
Blinding (performance bias and detection bias)
Blinding of outcome assessment (detection bias)
Incomplete outcome data (attrition bias)
Intention-to-treat Analysis
Selective reporting (reporting bias)
Similarity of baseline characteristics?
Co-interventions avoided or similar?
Compliance acceptable?
Timing outcome assessments similar?
Andrade 2008
Berwick 1989
Cecchi 2010a
Costantino 2014
Dalichau 1999
Devasahayam 2014
Donchin 1990
Donzelli 2006
Dufour 2010
Durmus 2014
Garcia 2013
Heymans 2006
Hurri 1989
Jaromi 2012
Keijsers 1989
Keijsers 1990
Klaber Moffett 1986
Lankhorst 1983
Lønn 1999
Meng 2009
Morone 2011
Morone 2012
Nentwig 1990
Paolucci 2012a
Paolucci 2012b
Penttinen 2002
Postacchini 1988
Ribeiro 2008
Sahin 2011
Tavafian 2007

Caption

Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Sources of support

Internal sources

- Christopher Maher has a senior research fellowship by the National Health and Medical Research Council, Australia
- Patricia Parreira is supported by CAPES (Coordenação de Aperfeiçoamento de Pessoal de Nível Superior), Brazil
- Chung-Wei Christine Lin has a Career Development Fellowship from the National Health and Medical Research Council, Australia

External sources

- VU University Medical Center, Netherlands
- The George Institute for Global Health, Sydney Medical School, The University of Sydney, Australia

Feedback

Appendices

1 Glossary of terms

Bias: a systematic error, or deviation from the truth, in results or inferences. Biases can operate in either direction: different biases can lead to underestimation or overestimation of the true intervention effect. Control of bias in randomised controlled trials is necessary to reduce the risk of making incorrect conclusions about treatment effects.

Biomechanics: the study of muscular activity.

Ergonomics: the arranging of things people use in a way that makes their use safe and less painful.

Medical care: pain medication, physician counselling.

Meta-analysis: the statistical combination of results from two or more separate studies.

Metastasis: the spreading of cancer.

Neoplasm: tumour.

Osteoporosis: the thinning and weakening of bones which can lead to fractures.

Publication bias: the publication or non-publication of research findings, depending on the nature and direction of the results.

Scapulae: shoulder blade.

2 Search strategies

CENTRAL

Last searched 15 November 2016. The strategy was revised in 2011. Back pain was added to line 3 in 2015.

#1 MeSH descriptor: [Back Pain] explode all trees

#2 dorsalgia

#3 backache or back pain

#4 (lumbar near pain) or (coccyx) or (coccydynia) or (sciatica) or (spondylosis)

#5 MeSH descriptor: [Sciatica] explode all trees

#6 MeSH descriptor: [Spine] explode all trees

#7 MeSH descriptor: [Spinal Diseases] explode all trees

#8 (lumbago) or (discitis) or (disc near herniat*)

#9 spinal fusion

#10 facet near joint*

#11 MeSH descriptor: [Intervertebral Disc] explode all trees

#12 postlaminectomy

#13 arachnoiditis

#14 failed near back

#15 MeSH descriptor: [Cauda Equina] explode all trees

#16 lumbar near vertebra*

#17 spinal near stenosis

#18 slipped near (disc* or disk*)

#19 degenerat* near (disc* or disk*)

#20 stenosis near (spine or root or spinal)

#21 displace* near (disc* or disk*)

#22 prolap* near (disc* or disk*)

#23 (#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)

#24 "back school"

#25 (#23 and #24)

#26 #25 in Trials

#27 #26 Publication Year from 2015 to 2016

January 2009 strategy

#1 MeSH descriptor Back explode all trees

#2 MeSH descriptor Buttocks, this term only

#3 MeSH descriptor Leg, this term only

#4 MeSH descriptor Back Pain explode tree 1

#5 MeSH descriptor Back Injuries explode all trees

#6 MeSH descriptor Low Back Pain, this term only

#7 MeSH descriptor Sciatica, this term only

#8 (low next back next pain)

#9 (lbp)

#10 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9)

#11 (back school):ti,ab,kw

#12 (#10 AND #11), from 2007 to 2009

MEDLINE

Last searched 15 November 2016. Back pain was added to line 17 in 2015. Lines 5, 22, 25 and 26 were added in 2014.

1 randomized controlled trial.pt.

2 controlled clinical trial.pt.

3 comparative study.pt.

4 clinical trial.pt.

5 pragmatic clinical trial.pt.

6 randomized.ab.

7 placebo.ab,ti.

8 drug therapy.fs.

9 randomly.ab,ti.

10 trial.ab,ti.

11 groups.ab,ti.

12 or/1-11

13 (animals not (humans and animals)).sh.

14 12 not 13

15 dorsalgia.ti,ab.

16 exp Back Pain/

17 (backache or back pain).ti,ab.

18 (lumbar adj pain).ti,ab.

19 coccyx.ti,ab.

20 coccydynia.ti,ab.

21 sciatica.ti,ab.

22 exp sciatic neuropathy/

23 spondylosis.ti,ab.

24 lumbago.ti,ab.

25 back disorder$.ti,ab.

26 exp Back Muscles/

27 or/15-26

28 back school.mp.

29 14 and 27 and 28

30 limit 29 to yr=2015-2016

31 limit 29 to ed=20150804-20161115

32 30 or 31

The June 2011 search for MEDLINE used a different entry date filter to current strategy:

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. exp Low Back Pain/
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. or/12-22
24. back school.mp.
25. 11 and 24 and 23
26. limit 25 to yr="2009 - 2011"
27. 2009$.ed.
28. 2010$.ed.
29. 2011$.ed.
30. 27 or 28 or 29
31. 25 and 30
32. 26 or 31

The April 2007 strategy for MEDLINE used a different study design filter to current 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. back school.mp.
26. 12 and 24 and 25
27. limit 26 to yr="2004 - 2007"

EMBASE

Last searched 15 November 2016. In March 2014, line 31 was changed from 14 and 30 to 14 or 30, line 47 was added, and the animal study filter (lines 32 to 36) was revised from the June 2011 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$)).mp.
28. trial.mp.
29. (versus or vs).mp.
30. or/15-29
31. 14 or 30
32. exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/
33. human/ or normal human/ or human cell/
34. 32 and 33
35. 32 not 34
36. 31 not 35
37. dorsalgia.mp.
38. back pain.mp.
39. exp BACKACHE/
40. (lumbar adj pain).mp.
41. coccyx.mp.
42. coccydynia.mp.
43. sciatica.mp.
44. ischialgia/
45. spondylosis.mp.
46. lumbago.mp.
47. back disorder$.ti,ab.
48. or/37-47
49. back school.mp.
50. 36 and 48 and 49
51. limit 50 to yr=2015-2016
52. limit 50 to dd=20150804-20161115

53. 51 or 52

The June 2011 strategy used a different animal study and entry date filter:

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$)).mp.
28. trial.mp.
29. (versus or vs).mp.
30. or/15-29
31. 14 and 30
32. human/
33. Nonhuman/
34. exp ANIMAL/
35. Animal Experiment/
36. 33 or 34 or 35
37. 32 not 36
38. 31 not 36
39. 37 and 38
40. 38 or 39
41. dorsalgia.mp.
42. back pain.mp.
43. exp BACKACHE/
44. (lumbar adj pain).mp.
45. coccyx.mp.
46. coccydynia.mp.
47. sciatica.mp.
48. exp ISCHIALGIA/
49. spondylosis.mp.
50. lumbago.mp.
51. exp Low back pain/
52. or/41-51
53. back school.mp.
54. 40 and 52 and 53
55. limit 54 to yr="2009 - 2011"
56. 2009$.em.
57. 2010$.em.
58. 2011$.em.
59. 56 or 57 or 58
60. 54 and 59
61. 55 or 60

CINAHL

Last searched 15 November 2016.

Back pain was added to line 27 in 2015. In 2014 , CINAHL was searched from inception to May 2007 using the current strategy to ensure records were up to date.

S47 S45 OR S46

S46 S44 and EM 20150804-20161115

S45 S42 AND S43Limiters - Published Date: 20150801-20161131

S44 S42 AND S43

S43 back school

S42 S24 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

S40 lumbago

S39 (MH "Spondylolysis")

S38 (MH "Spondylolisthesis")

S37 lumbar N2 vertebrae

S36 (MH "Lumbar Vertebrae")

S35 back disorder*

S34 coccydynia

S33 coccyx

S32 sciatica

S31 (MH "Sciatica")

S30 (MH "Coccyx")

S29 lumbar N5 pain

S28 lumbar W1 pain

S27 backache or back pain

S26 (MH "Back Pain+")

S25 dorsalgia

S24 S22 not S23

S23 (MH "Animals+")

S22 S21 or 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

S21 volunteer*

S20 prospectiv*

S19 control*

S18 followup stud*

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 W3 trial

S2 randomi?ed controlled trial*

S1 (MH "Clinical Trials+")

June 2011 search. Line S3 was changed from "clinical W8 trial" to "clinical W3 trial" and line S21 and S42 were added:

S51 S49 and S50 Limiters - Published Date from: 20090101-20111231

S50 "back school"

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 15 November 2016.

1 clinical trials/

2 controlled trial.mp.

3 RCT.mp.

4 Random*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]

5 (clin* adj3 trial).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]

6 (sing* adj2 blind*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]

7 (doub* adj2 blind*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]

8 placebo.mp. or exp Placebo/

9 latin square.mp.

10 (random* adj2 assign*).mp.

11 prospective studies/

12 (prospective adj stud*).mp.

13 (comparative adj stud*).mp.

14 treatment effectiveness evaluation/

15 (evaluation adj stud*).mp.

16 exp Posttreatment Followup/

17 follow?up stud*.mp.

18 or/1-17

19 back pain/

20 lumbar spinal cord/

21 (low adj back adj pain).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]

22 (back adj pain).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]

23 spinal column/

24 (lumbar adj2 vertebra*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]

25 coccyx.mp.

26 sciatica.mp.

27 lumbago.mp.

28 dorsalgia.mp.

29 back disorder*.mp.

30 "back (anatomy)"/

31 ((disc or disk) adj degenerat*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]

32 ((disc or disk) adj herniat*).mp.

33 ((disc or disk) adj prolapse*).mp.

34 (failed adj back).mp.

35 or/19-34

36 back school.mp.

37 18 and 35 and 36

38 limit 37 to yr=2015-2016

The June 15, 2011 search in Cambridge Scientific Abstracts (CSA)

((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) OR DE=(neck))) and(KW=(back school))

ClinicalTrials.gov

Last searched 15 November 2016

Basic search: “back school” and back pain

Received from 08/04/2015 to 11/15/2016

June 2011 search

Condition: back pain

AND

Intervention: back school

WHO ICTRP

Last searched 15 November 2016

Basic search: back school and back pain

June 2011 search

Condition: back pain

AND

Intervention: back school

PubMed

Searched August 4, 2015

((back pain OR backache OR coccydynia OR sciatica OR back disorder OR lumbago OR spondylosis) AND (back school) AND (random OR randomly OR randomized OR randomised OR placebo OR trial) AND (pubstatusaheadofprint OR publisher[sb] OR pubmednotmedline[sb]))

Filters activated: Publication date from 2014/03/04 to 2015/12/31

3 The GRADE approach to evidence synthesis

We will categorise the quality of evidence as follows.

- High: Further research is very unlikely to change either the estimate or confidence in the results.
- Moderate: Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.
- Low: Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.
- Very low: Any estimate of effect is very uncertain.

We will grade the evidence available to answer each subquestion on the domains in the following manner.

Risk of bias

Limitations in the study design and implementation may bias the estimates of the treatment effect. If studies suffer from any major limitation, the accuracy in the estimate of the effect and its recommendation can be affected. We will examine all studies on the following five types of biases.

1. Selection (random sequence generation, allocation concealment, group similarities at baseline): We will score this item as low risk of bias if two or more of these items are defined as having low risk.
2. Performance (blinding of participants, blinding of healthcare providers, co-interventions, and compliance with intervention):

We will score this item as low risk of bias if three or more of these items are defined as having low risk.

3. Attrition (dropouts and intention-to-treat analysis): We will score this item as low risk of bias if both of these items are defined as having low risk.
4. Measurement (blinding of the outcome assessors and timing of outcome assessment): We will score this item as low risk of bias if both of these items are defined as having low risk.
5. Reporting bias (selective reporting): We will score this item as low risk of bias if it is defined as having low risk.

We will define a study with a low risk of bias as having low risk of bias on four or more of these items.

Inconsistency

Inconsistency refers to an unexplained heterogeneity of results. Widely differing estimates of the treatment effect (i.e. heterogeneity or variability in results) across studies suggest true differences in underlying treatment effect. Inconsistency may arise from differences in populations (e.g. drugs may have larger relative effects in sicker populations), interventions (e.g. larger effects with higher drug doses), or outcomes (e.g. diminishing treatment effect with time). We will downgrade the quality of evidence as follows:

- by one level: when the heterogeneity or variability in results is large (e.g. I^2 above 80%);
- by two levels: when the heterogeneity or variability in results is large AND there was inconsistency arising from populations, interventions, or outcomes.

Indirectness

Indirect population, intervention, comparator, or outcome: the question being addressed in this systematic review differs from the available evidence regarding the population, intervention, comparator, or an outcome in the included randomised trial. We will downgrade the quality of evidence as follows:

- by one level: when there is indirectness in only one area;
- by two levels: when there is indirectness in two or more areas.

Imprecision

Results are imprecise when studies include relatively few participants and events and thus have wide confidence intervals around the estimate of the effect. In such cases we judge the quality of the evidence as lower than it otherwise would have been because of resulting uncertainty in the results. We consider each outcome separately.

For dichotomous outcomes

We will consider imprecision for either of the following two reasons.

1. There is only one study. When there is more than one study, the total number of events is less than 300 (a threshold rule-of-thumb value) (Mueller 2007).
2. The 95% confidence interval around the pooled or best estimate of effect includes both a) no effect and b) appreciable benefit or appreciable harm. The threshold for 'appreciable benefit' or 'appreciable harm' is a relative risk reduction or relative risk increase greater than 25%.

We will downgrade the quality of the evidence as follows:

- by one level: when there is imprecision due to (1) or (2);
- by two levels: when there is imprecision due to (1) and (2).

For continuous outcomes

We will consider imprecision for either of the following two reasons.

1. There is only one study. When there is more than one study, 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 deviation, representing a small effect).
2. The 95% confidence interval includes no effect and the upper or lower confidence limit crosses an effect size (standardised mean difference) of 0.5 in either direction.

We will downgrade the quality of the evidence as follows:

- by one level: when there is imprecision due to (1) or (2);
- by two levels: when there is imprecision due to (1) and (2).

Publication bias

Publication bias is a systematic underestimate or overestimate of the underlying beneficial or harmful effect due to the selective publication of studies. We will downgrade the quality of evidence by one level when the funnel plot suggests publication bias.

Chapter Six

An overview of clinical guidelines for the management of vertebral compression fracture: a systematic review

Chapter Three has been presented as:

Parreira PCS, Maher CG, Megale RZ, March L, Ferreira ML. *An overview of clinical guidelines for the management of vertebral compression fracture: a systematic review*. Spine J. 2017 Jul 21 pii: S1529-9430(17)30495-3 doi: 10.1016/j.spinee.2017.07.174. Reprinted with permission from with permission from Elsevier

.

Statement from co-authors confirming authorship contribution of the PhD Candidate

The co-authors of the paper: "Parreira PCS, Maher CG, Megale RZ, March L, Ferreira ML. *An overview of clinical guidelines for the management of vertebral compression fracture: a systematic review*. Spine J. 2017 Jul 21 pii: S1529-9430 (17) 30495-3"confirm that Patricia C S Parreira has made the primary contribution to this study in each of the following areas:

• Conception and design of the research

• Interpretation of findings

• Writing of the manuscript and critical appraisal of content

In addition to the statements above, in cases where I am not the corresponding author of a published item, permission to include the published material has been granted by the corresponding author.

Patricia do Carmo Silva Parreira _____Date: 08/07/2018

As supervisor for the candidature upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

Professor Chris Maher_____ Date: 08/07/2018

ELSEVIER

The Spine Journal ■■ (2017) ■■–■■

THE SPINE JOURNAL

Review Article

An overview of clinical guidelines for the management of vertebral compression fracture: a systematic review

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Received 17 April 2017; revised 7 July 2017; accepted 17 July 2017

Abstract

BACKGROUND CONTEXT: Vertebral compression fractures (VCFs) are the most common type of osteoporotic fracture comprising approximately 1.4 million cases worldwide. Clinical practice guidelines can be powerful tools for promoting evidence-based practice as they integrate research findings to support decision making. However, currently available clinical guidelines and recommendations, established by different medical societies, are sometimes contradictory.

PURPOSE: The aim of this study was to appraise the recommendations and the methodological quality of international clinical guidelines for the management of VCFs.

STUDY DESIGN: This is a systematic review of clinical guidelines for the management of VCF.

METHODS: Guidelines were selected by searching MEDLINE and PubMed, PEDro, CINAHL, and EMBASE electronic databases between 2010 and 2016. We also searched clinical practice guideline databases, including the National Guideline Clearinghouse and the Canadian Medical Association InfoBase. The methodological quality of the guidelines was assessed by two authors independently using the Appraisal of Guidelines, Research and Evaluation (AGREE) II Instrument. We also classified the strength of each recommendation as either strong (ie, based on high-quality studies with consistent findings for recommending for or against the intervention), weak (ie, based on a lack of compelling evidence resulting in uncertainty for benefit or potential harm), or expert consensus (ie, based on expert opinion of the working group rather than on scientific evidence). Guideline recommendations were grouped into diagnostic, conservative care, interventional care, and osteoporosis treatment and prevention of future fractures. Our study was prospectively registered on PROSPERO.

RESULTS: Four guidelines from three countries, published in the period 2010–2013, were included. In general, the quality was not satisfactory (50% or less of the maximum possible score). The domains scoring 50% or less of the maximum possible score were rigor of development, clarity of presentation, and applicability. The use of plain radiography or dual-energy X-ray

FDA device/drug status: Not applicable.

Author disclosures: ***PCSP:*** Nothing to disclose. ***CGM:*** Nothing to disclose. ***RZM:*** Nothing to disclose. ***LM:*** Nothing to disclose. ***MLF:*** Nothing to disclose.

The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

Patricia C.S. Parreira is supported by CAPES (Coordenação de Aperfeiçoamento de Pessoal de Nível Superior), Brazil. Chris G. Maher is supported by the National Health and Medical Research Council of Australia (APP1103022). Manuela L. Ferreira is supported by the Sydney Medical Foundation/Sydney Medical School.

All authors were involved in the design of the study. PCSP, MLF, and CGM wrote the first draft. All authors approved the final version of the manuscript submitted for publication.

All authors have declared that they had no support from any organization for the submitted work, no financial relationships with any organizations that might have an interest in the submitted work in the previous 3 years, or any other relationships or activities that could appear to have influenced the submitted work.

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http://dx.doi.org/10.1016/j.spinee.2017.07.174

absorptiometry for diagnosis was recommended in two of the four guidelines. Vertebroplasty or kyphoplasty was recommended in three of the four guidelines. The recommendation for bed rest, trunk orthoses, electrical stimulation, and supervised or unsupervised exercise was inconsistent across the included guidelines.

CONCLUSIONS: The comparison of clinical guidelines for the management of VCF showed that diagnostic and therapeutic recommendations were generally inconsistent. The evidence available to guideline developers was limited in quantity and quality. Greater efforts are needed to improve the quality of the majority of guidelines.

Keywords: Clinical guidelines; Conservative care; Diagnosis; Intervention care; Recommendation; Systematic reviews; Vertebral compression fracture

Introduction

Compression fracture

Vertebral compression fractures (VCFs) are the most common type of osteoporotic fracture comprising approximately 1.4 million cases worldwide [1]. Vertebral compression fractures are more common in older adults because spine bone mineral density decreases steadily with age, with people having lost almost half of their axial bone mass by the time they reach their 80s [2,3]. Symptomatic VCFs often lead to severe spinal pain, spinal deformity [4,5], decreased mobility [4,5], and decreased pulmonary function [4,5], and can increase the risk of age-adjusted mortality [4,5]. To decrease this burden, evidence-based prevention and management are essential [2,3].

Clinical practice guidelines can be potent tools for helping evidence-based practice as they incorporate research findings to support decision making. These guidelines have been expected to facilitate more consistent, effective, and efficient medical practice, and ultimately improve health outcomes. However, currently available clinical guidelines and recommendations, established by different medical societies, are sometimes contradictory.

The aim of the present study was to present and compare the content of international clinical guidelines for the management of VCFs. These guidelines have been compared regarding the content of their recommendations, the target group, the guideline committee and its procedures, and the extent to which the recommendations are based on the available literature (the scientific evidence). We also appraise the methodological quality of the included guidelines.

Methods

Data sources

Guidelines in which VCF management was addressed were identified by searching MEDLINE and PubMed, PEDro, CINAHL, and EMBASE electronic databases. We also searched in guideline databases, including the National Guideline Clearinghouse and the Canadian Medical Association InfoBase. We screened the reference lists of relevant guidelines and used the Web of Science citation index to identify guidelines citing the previous guideline. The strategies can be found in Appendix 1.

Selection of guidelines

Two review authors independently screened titles and abstracts for potentially eligible studies and clearly ineligible records were excluded. We used full-text papers to determine the final inclusion in the review. We resolved disagreements between review authors through discussion or by the arbitration of a third review author. Evidence-based clinical practice guidelines were included if they satisfied the following criteria:

1. The clinical practice guideline was produced under the auspices of a health professional association or society, a public or private organization, a health-care organization or plan, or a government agency. A clinical practice guideline developed and issued by an individual or a group of individuals not officially sponsored or supported by one of the above types of organizations was not be included.
2. The clinical practice guideline was publicly available.
3. A systematic literature search and review of existing scientific evidence published in peer-reviewed journals was performed during the guideline development, or the guidelines were based on a systematic review published in the 4 years preceding the publication of the guideline.
4. The clinical practice guideline contained systematically developed statements that included recommendations, strategies, or information to guide decisions about the appropriate health care.
5. The clinical practice guideline was published in the last 7 years (2010–2016).

Quality assessment

All guidelines were reviewed independently by two authors and were scored for methodological quality according to the Appraisal of Guidelines, Research and Evaluation (AGREE) II instrument [6], which has been shown to be reliable for the assessment of the quality of clinical guidelines. This tool consists of 23 items organized in six domains so that each domain is intended to capture a separate dimension of guideline quality. Each item is rated on a seven-point scale. A score of 7 indicates that the

quality of reporting is exceptional, and all of the criteria and considerations articulated in the user's manual were met [6]. The score for each domain was calculated as follows: (obtained score−minimal possible score)/(maximal possible score−minimal possible score). As defined by AGREE II, we considered a clinical guideline as satisfactory if it scored at least 50% on all six domains. The AGREE II instrument can be found in Appendix 2.

Strength of recommendation

We classified the strength of each recommendation as either *strong*, based on high-quality studies with consistent findings for recommending for or against the intervention; *weak*, based on the lack of compelling evidence resulting in an uncertainty for benefit or potential harm; or expert *consensus*, based on expert opinion of the working group rather than on scientific evidence.

Results

Selection of guidelines

As shown in the Figure, the database search identified 442 documents. After two reviewers independently screened titles, abstracts, and full-texts according to the inclusion and exclusion criteria, four guidelines were selected for inclusion**.** The four guidelines included in the review were developed in the United States (2), Canada (1), and the United Kingdom (1). All guidelines were published in English. A description of all included guidelines is presented in Table 1.

Quality assessment

The AGREE II scores for each domain for each guideline are provided in Table 2. None of the four guidelines were considered satisfactory based on the AGREE II checklist (ie, none scored at least 50% for all domains). An evaluation of inter-rater reliability was performed for the AGREE II ratings and the intraclass correlation coefficient was 0.97 (95% confidence interval=0.94–0.98), showing a high level of reliability.

Scope and purpose

The score for the scope and purpose domain ranged from 53% to 94%. All guidelines described their overall objectives, health questions, and target populations.

Stakeholder involvement

The score for the stakeholder involvement domain ranged from 44% to 64%. Three [7–9] of the four guidelines had at least a score of 50% of the maximum possible score in this domain. Many guidelines lacked a description of how they included the views and preferences of patients or had not performed a test among target users.

Rigor of development

The score for the rigor of development domain ranged from 17% to 82%. Three [7,9,10] of the four guidelines scored less than 50% of the maximum possible score in this domain. Only

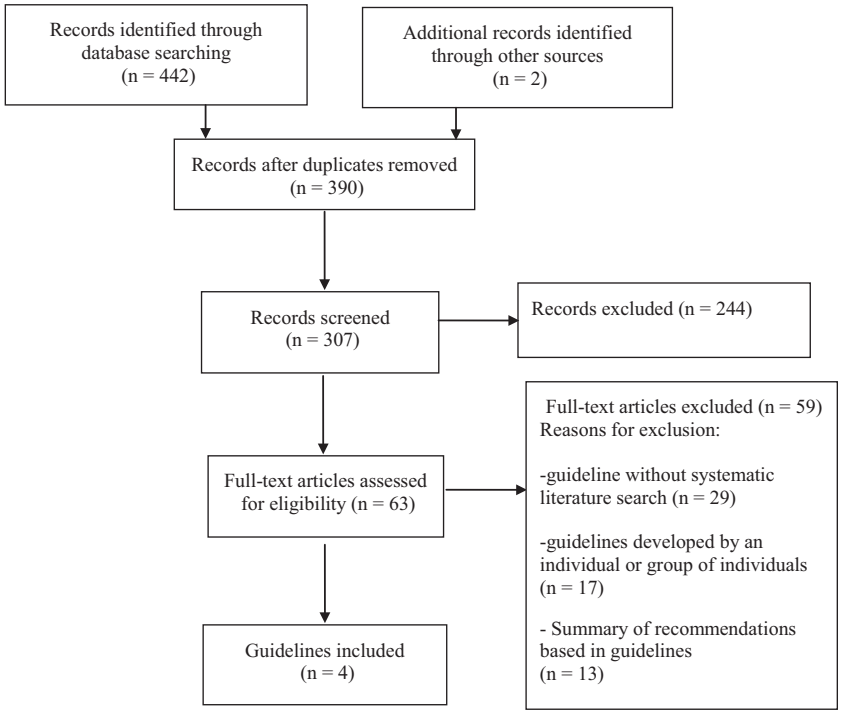

Figure. Selection of guidelines for inclusion in the systematic review.

Table 1
Clinical guideline recommendations regarding the diagnosis and the treatment of compression fracture and strength of recommendation

Guideline	Diagnosis	Conservative care		Intervention care	Osteoporosis treatment and prevention of future fractures
		Pharmacologic	Other		
American Academy of Orthopedic Surgeons [7] (United States, 2010)	Not considered in guideline	Calcitonin for 4 wk (weak evidence) Opioids (weak evidence)	Brace (weak evidence) Bed rest (weak evidence) Exercise (weak evidence) Electrical stimulation (weak evidence)	L2 nerve root block for acute vertebral compression fracture at L3 and L4 (weak evidence) Kyphoplasty (weak evidence) Vertebroplasty is not recommended (strong evidence)	Ibandronate and strontium ranelate to prevent future symptomatic fractures (strong evidence)
National Institute for Health and Care Excellence Guidelines [8] (NICE) (United Kingdom, 2013)	Not considered in guideline	Pain medication (weak evidence)	Bed rest (weak evidence) Back braces (weak evidence)	Vertebroplasty or kyphoplasty (weak evidence)	Bisphosphonates (alendronate) to prevent future fractures (strong evidence)
Canadian Association of Radiologists [9] (Canada, 2011)	Spine radiography and DXA (expert consensus)	Not considered in guideline	Not considered in guideline	Not considered in guideline	"Pharmacologic therapy," regular active weight-bearing exercise* Calcium* Vitamin D daily*
American College of Radiology [10] (United States, 2010)	Spine radiography, DXA, magnetic resonance imaging, computed tomography (expert consensus)	Nonsteroidal anti-inflammatory drugs (weak evidence)	Medical management with or without methods of immobility (expert consensus)	Vertebroplasty or kyphoplasty (expert consensus)	Not considered in guideline

DXA, dual-energy X-ray absorptiometry.
* The methods used to formulate this recommendation are not clear in the guideline.

Table 2
Appraisal of Guidelines, Research and Evaluation II domain-standardized scores

Guideline	Scope and purpose (%)	Stakeholder involvement (%)	Rigor of development (%)	Clarity of presentation (%)	Applicability (%)	Editorial independence (%)
American Academy of Orthopedic Surgeons [7]	94	64	82	83	21	75
National Institute for Health and Care Excellence Guidelines [8] (NICE)	86	64	36	56	13	54
Canadian Association of Radiologists [9]	53	61	21	44	19	25
American College of Radiology [10]	78	44	17	8	19	8

one guideline [8] clearly described systematic methods of searching for evidence. No guideline described its procedures for updating guidelines.

Clarity of presentation

The score for the clarity of presentation domain ranged from 8% to 83%. Two [9,10] of the four guidelines scored less than 50% of the maximum possible score in this domain.

Applicability

Scores were lowest on the domain of applicability and ranged from 13% to 21%. No guideline systematically described the facilitators and barriers of its applications.

Editorial independence

The score for the editorial independence domain ranged from 8% to 75%. Two [7,8] of the four guidelines scored 50% of the maximum possible score in this domain and gave information on the editorial independence and described possible conflicts of interests.

Diagnostic recommendations

Table 1 compares the diagnostic classification and the recommendations on diagnostic procedures in the various guidelines. Diagnostic recommendations were provided in two [9,10] guidelines. Both guidelines recommended spine radiography or vertebral fracture assessment by dual-energy X-ray

absorptiometry (DXA). However, this recommendation was based only on expert consensus, or the methods used to formulate this recommendation are not clear in the guideline. The American College of Radiology [10] also recommended magnetic resonance imaging and computed tomography for the diagnostic of VCF in patients for whom vertebroplasty or kyphoplasty is being considered.

Conservative care

Recommendations for the prescription of calcitonin, opioids, and nonsteroidal anti-inflammatory drugs were inconsistent in the guidelines. Three guidelines recommended a different approach (based on weak evidence) and one guideline was silent on pharmacologic care. Two [7,8] guidelines recommended bed rest or a back brace for VCF based on weak evidence, and the other two made no recommendation on these interventions.

Interventional care

Based on weak evidence, three [7,8,10] guidelines recommended kyphoplasty when other interventions were not successful in improving the patient's outcomes. Based on weak evidence, vertebroplasty was recommended in two [8,10] of three guidelines. However, based on strong evidence, the American Academy of Orthopedic Surgeons [8] advised against vertebroplasty for osteoporotic spinal compression fracture. This recommendation was based on high-quality studies [11–14] with consistent findings recommending against the intervention. According to the American Academy of Orthopedic Surgeons [8], kyphoplasty is an option for patients who are diagnosed with an osteoporotic VCF and who are neurologically intact. Based on weak evidence, L2 nerve root block for acute VCF at L3 and L4 was recommended in one guideline [7].

Osteoporosis treatment and prevention of future fractures

The four guidelines provide different recommendations on the treatment of osteoporosis and the prevention of future fractures. Recommendations in two guidelines were confined to drugs, ibandronate and strontium ranelate in one guideline [7] and bisphosphonates (alendronate) in the other [8], both recommendations based on strong evidence. One guideline provided non-descript advice on drugs ("pharmacologic therapy"), promotion of exercise, and calcium and vitamin D. The final guideline provided no recommendations in this area.

Discussion

Statement of principal findings

We evaluated the consistency of the recommendations of clinical guidelines for the management of VCF and the rigor of their development. Our review found that, based on the AGREE II instrument, none of the clinical guidelines was of overall satisfactory quality. Our results showed that two [9,10] of four guidelines endorsed spine radiography and dual-energy X-ray absorptiometry for the diagnosis of VCF based on expert consensus; two [7,8] of four guidelines recommended bed rest or a back brace for VCF based on weak evidence. Other conservative treatment such as electrical stimulation and exercise programs had inconsistent recommendations. Our results also found that three [7,8,10] guidelines (based on weak evidence) recommended kyphoplasty; two of the guidelines [8,10] recommended vertebroplasty for interventional care. Two [7,8] of the four guidelines recommended drugs for the reduction of future incident fractures based on strong evidence.

Differences between evidence and recommendation

Our results suggest there is currently no consensus on clinical recommendations for the management of pain in VCFs. Moreover, in only one guideline [8], the recommendations were directly linked to the supporting evidence. This may explain the inconsistency between the recommendations and the supporting evidence. For example, two [7,10] of the four guidelines claim that vertebroplasty is an appropriate therapy for the treatment of painful VCF refractory to conservative care. However, this recommendation is explicitly not endorsed by the American Academy of Orthopedic Surgeons [8]. A recent review [11] concluded that there is a need for a more definitive evidence to establish the effectiveness of this surgical procedure.

Guideline evaluation

Overall, none of the guidelines was of satisfactory quality. The domains with the lowest scores were rigor of development and applicability. Although the AGREE II instrument provides six independent domains, the "rigor of development" domain is arguably a key measure of guideline quality across all domains as it evaluates the robustness of the guideline development process. Likewise, the "applicability" domain is key to assessing the translational capacity of each guideline. However, in our study, none of the included guidelines described the facilitators and barriers of implementation into clinical practice, potentially limiting their ability to improve health outcomes.

Strengths and weaknesses of the study

A strength of this review was that, to our knowledge, no previous studies have assessed the quantity and the quality of guidelines on VCFs. Our results identified a number of shortcomings in the available evidence for this important area of practice. Another strength of this review was that we searched seven electronic databases with a broad search strategy without making language restrictions. We ensured transparency of the methods by prospectively registering the study protocol on PROSPERO. The weakness of this review is that clinical

guidelines are sometimes published in local databases and, as a consequence, are not included in our review.

Unanswered questions and future research

VCFs are an increasing public health problem with serious clinical consequences and impose a considerable impact on patients' quality of life. However, the consequences and management of VCFs may have been considerably underestimated by researchers and clinicians. Our results found that the recommendations made in the included guidelines varied, probably because of the lack of high-quality studies on the management of VCF. In our view, the most important direction for future research would be to conduct randomized, blinded, controlled trials to determine which treatments are efficacious and safe for patients with VCF. This seems particularly justified for conservative and intervention care, as the results of existing trials did not clearly confirm the best approach in patients with VCF and there seems to be a reasonable chance that new, high-quality trials will clarify this uncertainty.

Appendix 1:

Medline Final: 168

Osteoporotic fractures.mp or Osteoporotic Fractures/ or Fractures, Bone/
(compress* adj3 fracture*).ti,ab
Lumbar Vertebrae.mp or Lumbar Vertebrae/
Thoracic Vertebrae.mp or Thoracic Vertebrae/
Spinal fractures.mp or Spinal fractures/
Vertebral compression fracture.ti,ab
verteb* fracture*.ti,ab
osteopor* spine fracture*.ti,ab
osteopor* vertebra*.ti,ab
spinal compress* fracture .ti,ab
vertebra* adj3 compression adj3 fracture*.ti,ab
(fragility adj3 fracture).ti,ab
Practice guideline'
"Clinical practice guideline"
CINAHL (Ovid)=0
Fractures, vertebral compression
Fractures, compression
Spinal fractures
Osteoporosis/[complications] OR osteoporosis, postmenopausal
"Lumbar Vertebrae".ti,ab
"verteb* compression".ti,ab
"verteb* fracture*".ti,ab,su
"osteopor* fracture*".ti,ab
"osteopor* vertebra*".ti,ab
(compress* adj3 fracture*).ti,ab,su
"spinal compress*".ti,ab
(vertebra* adj3 compression adj3 fracture*).ti,ab,su
"spinal fracture*".ti,ab
Guideline
Practice guideline
Clinical practice guideline

Embase (Ovid)=249
Vertebra fracture
(Verteb$ adj3 compression).ti,ab
(osteopor$ adj5 fracture).ti,ab
(osteopor$ adj5 compress$).mp
(verteb$ adj3 fracture$).ti,ab
(spin$ adj3 fracture$).C
(lumbar adj3 fracture$).ti,ab
(thoracic adj3 fracture$).ti,ab
(compress$ adj3 fracture$).ti,ab
"Vertebral compression fracture$".mp
"Clinical practice guideline" ti,ab

PEDro

Web of Science- online Web of Knowledge

Topic=("vertebral compression fracture*" OR "Verteb* compression*" OR "verteb* fracture*" OR "spinal compression fracture*")

Appendix 2: AGREE II instrument (Appraisal of Guidelines, Research and Evaluation)

Domain 1: scope and purpose

1 The overall objective(s) of the guideline is (are) specifically described.
2 The health question(s) covered by the guideline is (are) specifically described.
3 The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

Domain 2: stakeholder involvement

4 The guideline development group includes individuals from all the relevant professional groups.
5 The views and preferences of the target population (patients, public, etc.) have been sought.
6 The target users of the guideline are clearly defined.

Domain 3: rigour of development

7 Systematic methods were used to search for evidence.
8 The criteria for selecting the evidence are clearly described.
9 The strengths and limitations of the body of evidence are clearly described.
10 The methods for formulating the recommendations are clearly described.
11 The health benefits, side effects and risks have been considered in formulating the recommendations.
12 There is an explicit link between the recommendations and the supporting evidence.
13 The guideline has been externally reviewed by experts prior to its publication.
14 A procedure for updating the guideline is provided.

Domain 4: clarity of presentation

15 The recommendations are specific and unambiguous.
16 The different options for management of the condition or health issue are clearly presented.
17 Key recommendations are easily identifiable.

Domain 5: applicability

18 The guideline describes facilitators and barriers to its application.
19 The guideline provides advice and/or tools on how the recommendations can be put into practice.
20 The potential resource implications of applying the recommendations have been considered.
21 The guideline presents monitoring and/or auditing criteria.

Domain 6: editorial independence

22 The views of the funding body have not influenced the content of the guideline.
23 Competing interests of members of the guideline development group have been recorded and addressed.

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Chapter Seven

Evolution of guideline-endorsed red flags to screen for fracture in patients presenting with low back pain

Chapter Seven has been submitted as:

Parreira PCS, Maher CG, Traeger AC, Hancock M, Downie A, Koes BW, Ferreira ML. *Evolution of guideline-endorsed red flags to screen for fracture in patients presenting with low back pain*. This chapter has been formatted according to the guidelines from *The British Journal of Sports Medicine.*

Statement from co-authors confirming authorship contribution of the PhD Candidate

The co-authors of the paper: *"Parreira PCS, Maher CG, Traeger AC, Hancock M, Downie A, Koes BW, Ferreira ML. Evolution of guideline-endorsed red flags to screen for fracture in patients presenting with low back pain* (submitted to *British Journal of Sports Medicine)* confirm that Patricia C S Parreira has made the primary contribution to this study in each of the following areas:

• Conception and design of the research

• Interpretation of findings

• Writing of the manuscript and critical appraisal of content

In addition to the statements above, in cases where I am not the corresponding author of a published item, permission to include the published material has been granted by the corresponding author.

Patricia do Carmo Silva Parreira _____ Date: 08/07/2018

As supervisor for the candidature upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

Professor Chris Maher_____ Date: 08/07/2018

Abstract

Objectives: 1) Describe the evolution of guideline-endorsed red flags for fracture in patients presenting with low back pain (LBP), 2) Evaluate agreement between guidelines, and 3) Evaluate the extent to which recommendations are accompanied by information on diagnostic accuracy of endorsed red flags.

Design: Systematic review

Data sources: MEDLINE and PubMed, PEDro, CINAHL, and EMBASE electronic databases. We also searched in guideline databases, including the *National Guideline Clearinghouse* and *Canadian Medical Association Infobase*.

Eligibility criteria for selecting studies: Evidence-based clinical practice guidelines.

Data extraction: Two review authors independently extracted the following data: health professional association or society producing guideline, year of publication, the precise wording of endorsed red flag for vertebral fracture, recommendations for diagnostic work-up if fracture is suspected, if the guidelines substantiates the recommendation with citation to a primary diagnostic study or diagnostic review, if the guideline provides any diagnostic accuracy data.

Results: 79 guidelines from 28 countries published from 1987 to 2017 were included. A total of 11 discrete red flags were reported across 71 guidelines; 8 guidelines did not provide any red flags for fracture. The most commonly recommended red flags were older age (75% of guidelines), use of steroids (64%), trauma (57%) and osteoporosis (42%). The red flags that were less frequently reported were night pain (4%) and previous fracture (5%). Agreement between guidelines in endorsing red flags was only fair; Kappa Fleiss Coefficient= 0.32. Only 9 of the 79 guidelines (11%) substantiated their red flag recommendations by citation to a primary diagnostic study or diagnostic review and only 9 (11%) provided diagnostic accuracy data (e.g. likelihood ratios). Regarding the evolution of red flags, older age, trauma,

and osteoporosis were the first red flags endorsed (in 1994); non-mechanical pain, thoracic pain and use of steroids were described in 1996; night pain was endorsed in 1997, female gender and constant pain in 2000; previous fracture in 2003. Regarding the recommendations for further diagnostic workup, 60% of clinical practice guidelines recommended plain radiographs; 33% recommended magnetic resonance imaging, 30% recommended computed tomography and 13% recommended bone scan.

Conclusion: The number of red flags endorsed in guidelines to screen for fracture has risen over time; most guidelines do not endorse the same set of red flags and most recommendations are not supported by research or accompanied by diagnostic accuracy data.

Systematic review registration: PROSPERO registration number CRD42017065614

What this paper adds

What is already known on this subject?

- Clinical practice guidelines endorse red flags as the ideal method to identify patients with a higher likelihood of vertebral fracture.
- The total number of red flags endorsed in clinical guidelines is large.

What this study adds?

- The number of red flags endorsed in guidelines to screen for fracture has risen over time.
- Most guidelines do not endorse the same set of red flags.
- Most red flags presented in guidelines are not supported by research or accompanied by diagnostic accuracy data.

1. Background

Low back pain (LBP) is a leading cause of disability worldwide and is most commonly treated in primary health care settings.[1 2] While the majority of patients with this condition are diagnosed with non-specific LBP, in a small proportion of patients (<1% in primary care) the pain is the result of serious pathology.[3] The most common of these serious pathologies is vertebral fracture[4-6] followed by malignancy, infection, and inflammatory disease.[4] Identifying patients with an increased likelihood of vertebral fracture is a key objective of the clinical assessment for patients with LBP.[4]

Clinical guidelines endorse red flags as the ideal method to identify patients with a higher likelihood of vertebral fractures who then require further diagnostic work-up.[7 8] . Examples of red flags used to screen for vertebral fractures include a recent history of trauma and older age.[5] Inspection of clinical guidelines however reveals that guidelines usually do not endorse the same set of red flags and there is typically no information on diagnostic accuracy of the endorsed red flags.

The earliest report on red flags for vertebral fracture was published in 1872[9] and the first recognised clinical guideline for the management of acute low back pain containing recommendations regarding vertebral fracture did not appear until 1994.[10] Since then, numerous guidelines have been published around the world endorsing a range of red flags for vertebral fracture. It is not known if these recommendations are consistent across guidelines or based upon evidence. Therefore, the purpose of this study was: 1) Describe the evolution of guideline-endorsed red flags for fracture in patients presenting with low back pain (LBP), 2) Evaluate consistency between guidelines, and 3) Evaluate the extent to which

recommendations are accompanied by information on diagnostic accuracy of endorsed red flags.

2. Methods

2.1. Data sources

To locate LBP guidelines which endorse red flags for vertebral fracture in patients presenting with LBP we searched MEDLINE and PubMed, PEDro, CINAHL, and EMBASE electronic databases. We also searched in guideline databases, including the *National Guideline Clearinghouse* and *Canadian Medical Association Infobase*. Detailed search strategies used for each database are described in Appendix 1. The reference lists of relevant guidelines were screened and we used Web of Science citation index to identify guidelines citing other previous guidelines. There were no restrictions on date of publication. Guidelines in any language were considered, and included non-English language guidelines if a translation could be obtained.

2.2. Selection of guidelines

Two review authors independently screened titles and abstracts for potentially eligible studies and clearly ineligible records were excluded. Full-text papers were used to determine eligibility for inclusion in the review. The disagreements between review authors were resolved through discussion or by the arbitration of a third review author. Only one guideline was included per country per year. When one country had more than one guideline per year, the most recent multidisciplinary guideline was selected. Clinical practice guidelines were included if they satisfied all of the PEDro criteria for evidence-based clinical practice guidelines (points 1-4 below):

1. The clinical practice guideline was produced under the auspices of a health professional association or society, public or private organisation, health care organisation or plan, or government agency. Clinical practice guidelines developed and issued by an individual or group of individuals not officially sponsored or supported by one of the above types of organisations were not included.
2. The clinical practice guideline was publicly available.
3. A systematic literature search and review of existing scientific evidence published in peer-reviewed journals was performed during the guideline development OR the guidelines were based on a systematic review published in the four years preceding publication of the guideline.
4. The clinical practice guideline contained systematically developed statements that included recommendations, strategies, or information to guide decisions about appropriate health care.

2.3. Data extraction and management

Two review authors (PP and AT) independently extracted the data using standardised data extraction forms. The following data were extracted: (1) health professional association or society producing guideline, (2) year of publication, (3) the precise wording of endorsed red flag for vertebral fracture, (4) recommendations for diagnostic work-up if fracture is suspected, (5) if the guidelines substantiates the recommendation with citation to a primary diagnostic study or diagnostic review, (6) if the guideline provides any diagnostic accuracy data. The data from the guidelines were presented in a table. In the columns were included each discrete red flag for vertebral fracture listed in a guideline. In the rows were listed all guidelines chronologically beginning with the earliest published guideline. For each cell in the table we noted yes or no to signify whether that specific red flag was endorsed by that

guideline. The agreement among the guidelines in their endorsement of red flags was evaluated using Fleiss' Kappa[67] (Poor agreement= <0.00; Slight agreement= 0.00-0.20; Fair agreement= 0.21-0.40; Moderate agreement= 0.41-0.60; Substantial agreement= 0.61-0.80; Almost Perfect agreement= 0.81-1.00).

3. Results

3.1. Selection of guidelines

As shown in **Fig. 1**, the database search identified 1967 documents. After two reviewers (PP and AT) independently screened titles, abstracts and full-texts according to the inclusion and exclusion criteria, 79 guidelines were selected for inclusion**.** Clinical guidelines from 28 different countries were included in this review. The guidelines were published between 1987[12] and 2017,[13-17] with the publication date of one guideline not specified in the document (Malaysia)[18]. Only 32 of the 79 guidelines explicitly nominated red flags to screen for fracture, with the remainder nominating red flags for serious pathology in general. In the latter case we considered the following red flags as alerting features for fracture (older age, a recent history of trauma; prolonged use of corticosteroids; and osteoporosis) and coded their presence as a yes in the matrix.

3.2. Guideline Committee

The various committees responsible for the development and publication of guidelines appear to be different in size and in the professional disciplines involved. The number of members varied from 7 to 31.

3.3. Evolution and consistency of the guidelines

We noted a total of 11 discrete red flags reported in a total of 71 guidelines; eight guidelines did not provide any red flags for fracture. Older age, trauma, and osteoporosis were the first red flags endorsed; being endorsed in the 1994 US guideline;[10] non-mechanical pain, thoracic pain,[19] deformity[20] and use of steroids[21] were endorsed in 1996; in 1997, night pain[22] was endorsed as a red flag. Some red flags emerged in the 2000s: female gender[23] and constant pain[24] in 2000; previous fracture[25] in 2003. The red flags most commonly referred to in the guidelines were: older age (the cut-off varied between 50 and over 70 years) (n=62/79, 78%), use of steroids (n=53/79, 67%), trauma (n=47/79, 59%) and osteoporosis (n=35/79, 44%). The red flags that were less frequently endorsed were night pain (n=3, 4%) and previous fracture (n=4, 5%). Only five of the included guidelines (6%) recommended combinations of red flags. Comparing the guidelines, there is only fair overall consistency among them (Kappa Fleiss Coefficient= 0.317). **Table 1** shows the evolution of guideline-endorsed red flags in patients presenting with LBP.

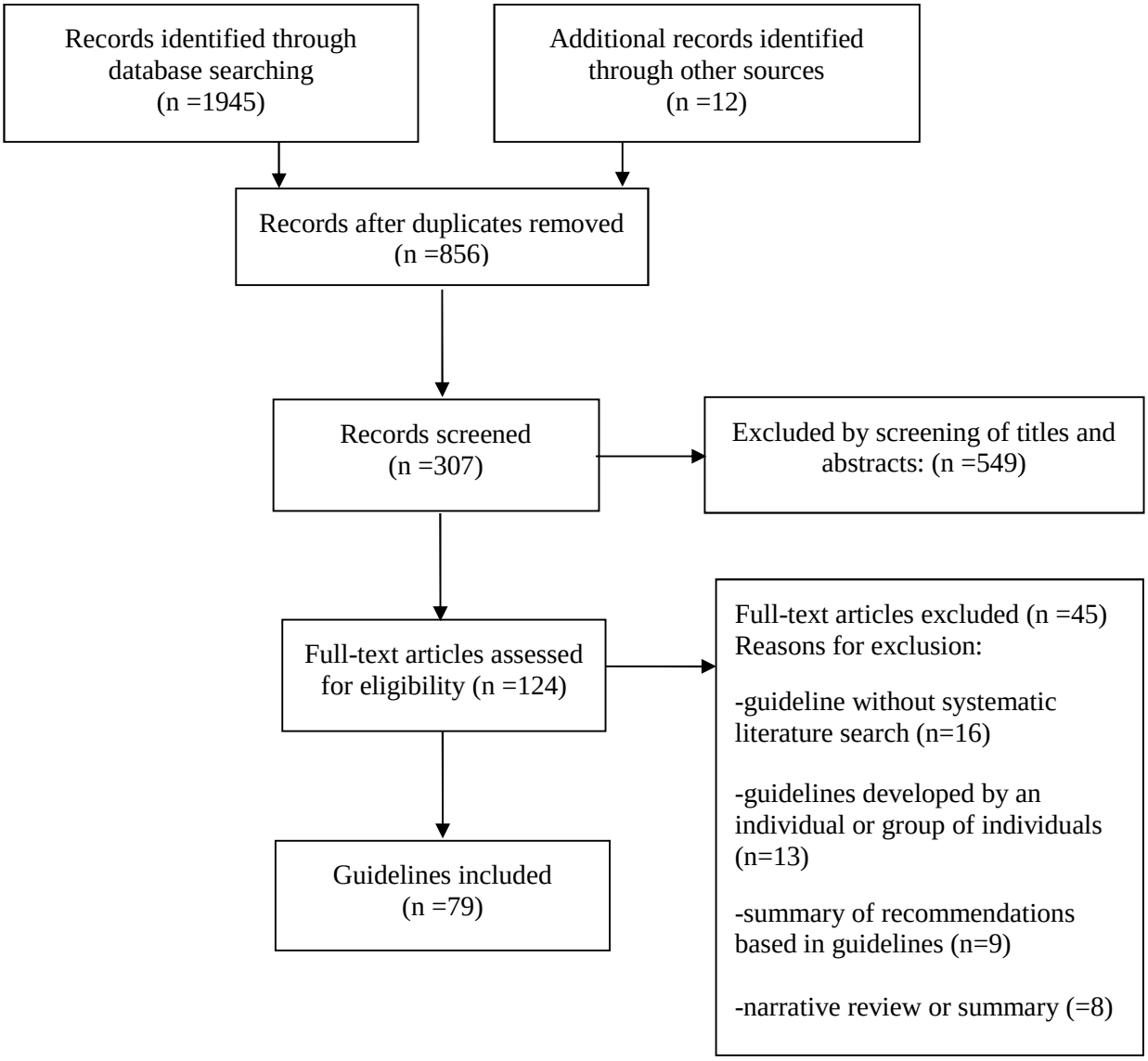

Figure 1: Selection of guidelines for inclusion in the systematic review.

Table 1. Evolution of guideline-endorsed red flags

Country, year	Red Flags											
	Older Age	Trauma	Use of steroids	Osteoporosis	Pain				Female Gender	Deformity	Previous fracture	Combination of flags
					Thoracic	Night	Non-mechanical	Constant				
*Canada, 1987[12]												
USA, 1994[10]	✓	✓		✓								✓
USA, 1995[26]	✓	✓		✓								✓
**Netherland, 1996[21]	✓		✓									
*USA, 1996[27]												
**United Kingdom, 1996[28]	✓	✓	✓		✓		✓			✓		
***Israel, 1996[29]												
**New Zealand, 1997[22]	✓	✓	✓			✓						
**Germany, 1997[30]		✓	✓									
**Denmark, 1998[31]	✓	✓		✓								
**Switzerland, 1998[32]	✓	✓										
Australia, 1999[33]	✓	✓	✓									
*Denmark, 1999[34]												
**Finland, 1999[35]	✓		✓	✓						✓		
France, 2000[36]	✓	✓	✓									
**United Kingdom, 2000[37]	✓	✓		✓				✓		✓		
**Sweden, 2000[38]	✓	✓		✓								
*USA, 2001[39]												
**Norway, 2002[40]	✓		✓	✓	✓			✓				
**Netherlands, 2003[41]	✓	✓	✓									
Australia, 2003[25]	✓	✓	✓	✓							✓	✓
**Denmark, 2003[42]	✓	✓		✓								
**Germany, 2004[43]	✓	✓	✓	✓								
**New Zealand, 2004[44]	✓	✓	✓			✓						
**Netherland, 2004[45]	✓		✓									
**Spain, 2005[46]	✓	✓	✓	✓					✓			
**Belgium, 2006[47]	✓		✓		✓		✓					
USA, 2006[48]	✓		✓				✓	✓				
**Europe, 2006[24]	✓	✓	✓					✓				
Italy, 2006[49]	✓	✓	✓	✓		✓			✓		✓	
**Canada, 2007[50]	✓	✓	✓		✓	✓	✓					
USA, 2007[6]	✓		✓	✓								

**Austria, 2007[51]	✓	✓	✓	✓										
Spain, 2007[52]	✓	✓	✓	✓										
**Norway, 2007[53]	✓		✓	✓	✓			✓	✓					
Canada, 2008[54]	✓		✓						✓			✓		
****USA, 2008[55]	✓		✓											
United Kingdom, 2008[56]	✓		✓	✓					✓					✓
*USA, 2009[57]														
*Korea, 2009[58]														
USA, 2010[59]	✓	✓	✓	✓					✓					
Netherlands, 2010[60]	✓	✓	✓						✓	✓				
**Norway, 2010[61]	✓		✓	✓	✓			✓						
Germany, 2010[62]	✓	✓	✓	✓										
**Mexico, 2011[63]	✓	✓	✓		✓					✓				
**Austria, 2011[64]	✓	✓	✓	✓										
****Canada, 2011[65]	✓	✓								✓				
USA, 2011[66]	✓	✓	✓	✓										
**Philippine, 2011[67]	✓	✓			✓		✓							
Germany, 2012	✓	✓	✓	✓										
****USA, 2012[68]	✓	✓	✓						✓					
**Spain, 2012[69]	✓	✓			✓	✓				✓				
China, 2013[20]	✓	✓	✓	✓										✓
*Brazil, 2013[70]														
**USA, 2013[71]	✓	✓	✓	✓										
Netherlands, 2013[72]	✓	✓	✓				✓			✓	✓			
*United Kingdom,2013[73]														
Germany, 2013[74]	✓	✓	✓	✓										
Scotland, 2013[75]			✓											
USA, 2014 [76]		✓							✓					
**Finland, 2014[77]	✓		✓	✓										
Germany, 2014[78]	✓	✓		✓										
***Croatia, 2014[79]														
USA, 2015[80]	✓	✓		✓					✓					
South Africa, 2015[81]	✓	✓		✓										
****Canada, 2015[82]	✓	✓		✓										✓
**Finland, 2015[83]	✓			✓					✓	✓				
*Netherlands, 2015[84]														
*Spain, 2015[85]														
**Australia, 2016[86]	✓	✓		✓					✓					✓
USA, 2016[19]	✓	✓		✓					✓					
**Malaysia, accessed in 2017[18]	✓	✓												

*United Kingdom, 2016[87]						
**Germany, 2017[17]	✓	✓	✓			
*Denmark, 2017[14]						
**USA, 2017[15]			✓			
Belgium, 2017[13]	✓	✓	✓	✓		✓
**Finland, 2017[16]	✓		✓			✓

Cells shaded in grey correspond to red flag endorsed by citation to a primary diagnostic accuracy study or diagnostic review
*There is no recommendation for red flags for fracture
**Covers all serious pathologies, not fracture in isolation
***Translation was not possible
**** Guidelines that provided diagnostic accuracy data eg sensitivity/specificity, likelihood ratios

Table 1 also shows information on provision of diagnostic accuracy data by the guidelines to support endorsed red flags. Among the 79 guidelines included, only 9 (11%) guidelines substantiated recommended red flags by citation to a primary diagnostic accuracy study/diagnostic review and 9 guidelines (11%) provided diagnostic accuracy data (e.g. *sensitivity*, specificity, LR+, LR-).

3.4 Recommendations on diagnostic procedures in the guidelines

Table 2 describes recommendations from the 30 guidelines on further diagnostic work-up with cases of suspected vertebral fracture. Of these, 28 guidelines were consistent with the recommendations that medical history and physical examination should focus on the identification of red flags. In total, 60% (n=18) of the clinical guidelines recommended plain radiographs; 33% (n=10) recommended magnetic resonance imaging, 30% (n=9) recommended computed tomography and 13% (n=4) recommended bone scan.

Table 2. Guideline recommendations on diagnostic work-up to confirm vertebral fracture

Country, year	Medical history/ Physical examination	Recommended investigation in presence of red flags				
		Plain x-ray	Bone scan	Computed tomography	Magnetic Resonance Imaging	Other recommendation
*USA, 1994[10]	✓	✓	✓	✓	✓	
*USA, 1995[26]	✓	✓	✓	✓	✓	
Australia, 1999[33]	✓	✓	✓			
France, 2000[36]	✓					
Australia, 2003[25]	✓					✓**
USA, 2006[48]	✓					
Italy, 2006[49]		✓				
USA, 2007[6]	✓	✓				
Spain, 2007[52]	✓	✓				
Canada, 2008[54]	✓	✓			✓	
USA, 2008[55]	✓				✓	
United Kingdom, 2008	✓				✓	
USA, 2010[59]	✓	✓	✓	✓	✓	
Netherlands, 2010[60]	✓					
Germany, 2010	✓	✓				
Canada, 2011	✓	✓		✓	✓	
USA, 2011	✓	✓				
Germany, 2012[88]	✓	✓				
***USA, 2012[68]						
China, 2013[20]	✓					
Netherlands, 2013[72]	✓					✓
Germany, 2013[74]	✓	✓				
Scotland, 2013[75]	✓					
USA, 2014 [76]	✓	✓		✓	✓	
Germany, 2014[78]	✓					
Canada, 2015[82]				✓		
USA, 2015[80]		✓		✓	✓	
South Africa, 2015[81]	✓					
USA, 2016[19]	✓	✓		✓		
Belgium, 2017[13]	✓	✓		✓	✓	

*If after 10 days, fracture still suspected, or multiple sites of pain, consider bone scan and consultation before defining anatomy with CT

**Appropriate investigations are indicated in cases of acute low back pain when alerting features (‘red flags’) of serious conditions are present¨.

***The therapist should inform the patient of this, and advise them to contact their family doctor.

4. Discussion

Statement of principal findings

We located 83 guidelines endorsing a total of 11 red flags. The number of red flags endorsed in guidelines to screen for fracture has risen over time. In 1994 there were only three red flags endorsed and this rose to 11 by 2003. Beyond 2003, no additional red flags were suggested by guidelines. Only 30 clinical guidelines provided recommendations regarding further diagnostic workup in the presence of red flags, and of these, 60% recommended plain radiographs, 33% recommended magnetic resonance imaging, 30% recommended computed tomography, and 13% recommended bone scan. Nevertheless, most guidelines do not endorse the same set of red flags (agreement between them was only fair; Kappa Fleiss Coefficient= 0.32) and most recommendations are not supported by research or accompanied by diagnostic accuracy data. Only 11% of the guidelines substantiated recommendations by citation to a primary diagnostic study or diagnostic review, and only 11% provided diagnostic accuracy data.

Strengths and weaknesses of the study

A strength of this review was that, to our knowledge, no previous studies had described the evolution of guideline-endorsed red flags for fracture in patients presenting with low back pain and evaluated the consistency between them. Another strength of this review was that we searched seven electronic databases with a broad search strategy and without language restrictions. We ensured transparency of the methods by prospectively registering our study protocol on PROSPERO. The weakness of this review is that clinical guidelines are sometimes published in local databases and, as a consequence, some may have been missed in our searches.

Strengths and weaknesses in relation to other studies

Our results are in agreement with previous studies[4 5 89 90] which concluded that the current evidence for the use of most red flags is weak. The Cochrane review[4] of red

flags for fracture only endorses 3 of the 11 red flags included in this review (prolonged use of corticosteroids, significant trauma, and age > 74), but also noted that estimates of likelihood ratios are imprecise. The only red flag that appeared informative in the Cochrane review ('presence of a contusion or abrasion') was absent from all guidelines. In addition, most guidelines recommend further investigation when any red flag is present, a recommendation that has been criticised because of the high risk of false positive findings.[89 90] The high prevalence of false positives is well illustrated in a longitudinal study[91] of 482 patients attending a back pain triage clinic; a total of 213 out of 482 had night pain, but none were diagnosed with a serious pathology. Possibly, part of the problem is considering a single red flag in isolation.

Previous studies have shown that a more useful approach is to rely on a combination of red flags to identify individuals who require further diagnostic work-up. Downie and colleagues[92] synthesised two Cochrane diagnostic systematic reviews and noted that the presence of multiple red flags increased the probability of fracture to between 42% to 90%. Another study[3] with 1172 patients presenting low back pain showed that the probability of fracture increased from 4% (pre-test) to 90% (95% CI 34–99 %) with the presence of three red flags. However, we found that only 7 of the 79 guidelines included in this review recommended the combination of red flags.

Interpretation of the study: Possible explanations and implications for clinicians and policymakers

Our findings suggest that guideline developers need to pay more attention to diagnostic research when framing recommendations for the use of red flags and that many existing guidelines need urgent revision. We would also advise clinicians to be cautious in using

red flags as alerting features for those patients who require further diagnostic work-up. There are important consequences if red flags are uncritically applied in clinical care. Adopting red flags that have high false positive rates (e.g. night pain)[91] will encourage unnecessary imaging. The use of red flags that are uninformative (e.g. female gender, age >50) may mean that patients with fractures could be missed. The inconsistency between guidelines with regard to red flags and diagnostic work-up creates uncertainty for clinicians managing these patients.[25, 26]

Unanswered questions and future research

The weak evidence for red flags creates uncertainty over the usefulness of them in clinical practice[4 89 90 93]. Some commentators suggest that screening for red flags is a popular idea that did not work and should be removed from guidelines.[89 90 93] Our review supports the use of red flags with caution as the majority of them is based on evidence from singles studies[4]. Therefore, an important extension of our research would be to evaluate combinations of red flags. Few studies[92 93] have reported on the accuracy of combinations of factors, and none have been validated in independent samples. Furthermore, our review showed that most guidelines contain little information on the diagnostic accuracy of the red flags. This lack of strong evidence to support the diagnostic capacity of the red flags is concerning and highlights the need for more high-quality diagnostic research on the topic.

Figure Legends

Appendix 1 Literature searches

Contributors: All authors were involved in the design of the study. PP, MLF and CM wrote the first draft. All authors have approved the final version of the manuscript submitted for publication.

Funding: Patricia C. S. Parreira is supported by CAPES (Coordenação de Aperfeiçoamento de Pessoal de Nível Superior), Brazil. Chris Maher is supported by National Health and Medical Research Council of Australia. Manuela L. Ferreira holds a Sydney Medical Foundation Fellowship/Sydney Medical School and is supported by the National Health and Medical Research Council of Australia.

Competing interests: All authors have declared: no support from any organization for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years; any other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: Not required.

Data sharing: No additional data.

Transparency: The lead author (Patricia CS Parreira) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; no important aspects of the study have been omitted.

Appendix 1 (date of the searches: 12/06/2018)

EMBASE search strategy

1 Index test: clinical red flags

’medical histor y taking’/e xp OR ’history’/de OR history OR ’red flag’ OR ’red flags’ OR ’ physical examination’/exp OR ’physical

examination’ OR ’function test’/de OR ’ function test’ OR ’physical test’ OR (clinical OR clinically AND (’diagnosis’/de OR sign OR

signs OR significance OR symptom$ OR parameter$ OR assessment OR finding$ OR evaluat$ O R indication$ OR examination$))

OR ’radiography’/exp OR ’radionuclide’/exp AND [humans]/lim

2. Pop ulation: low-back pain and anatomical lo cation

back AND ’pain’/exp OR ’back pain’ OR ’low back’ AND ’pain’/e xp OR ’low back pain’ OR ’sciatica’/exp OR sciatica OR backache

OR coccyx OR coccydynia OR dorsalgia OR ’lumbar pain’ OR spondylosis OR lumbago AND [humans]/lim

3. Target condition: vertebral fracture

’fractures, bone’/exp OR ’fractures, stress’/exp OR ’fractures, spontaneous’/exp OR ’fractures, compression’/exp OR ’fractures, closed’/

exp OR fracture$ OR ’spinal injuries’/exp OR ’spinal diseases’/exp OR ’ wounds and injuries’ /exp OR trauma$ OR injury AND

[humans]/lim

4. Exclusion criteria: case reports, animal studies

’case report’ AND [humans]/lim

Search co mbination

1 AND 2 AND 3 NOT 4

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Appendix 1. Search strategy

1 Index test: clinical red flags

"Medical History Taking"[mesh] OR history[tw] OR "red flag"[tw] OR "red flags" OR Physical examination[mesh] OR "physical examination"[tw] OR "function test"[tw] OR "physical test"[tw] OR ((clinical[tw] OR clinically[tw]) AND (diagnosis[tw] OR sign[tw] OR signs[tw] OR significance[tw] OR symptom*[tw] OR parameter*[tw] OR assessment[tw] OR finding*[tw] OR evaluat*[tw] OR indication*[tw] OR

examination*[tw])) OR (ra[sh] OR ri[sh]) OR “Wounds and Injuries”[mesh] OR trauma[tw] OR injury[tw] OR “Accidental Falls”[mesh]

2. Population: low-back pain and anatomical location

(back pain[mesh] OR sciatica[mesh] OR “back ache”[tw] OR backache[tw] OR “back pain”[tw] OR dorsalgia[tw] OR lumbago[tw] OR sciatica[tw] OR Pain[mesh] OR pain[tw] OR ache*[tw] OR aching[tw] OR complaint*[tw] OR dysfunction*[tw] OR disabil*[tw] OR neuralgia[tw]) AND (Back[mesh] OR spine[mesh] OR back[ti] OR lowback[tw] OR lumbar[tw] OR lumba*[tw] OR lumbo*[tw] OR sciatic*[tw] OR ischia*[tw] OR sacroilia*[tw] OR spine[tw] OR spinal[tw] OR radicular[tw] OR “nerve root”[tw] OR “nerve roots”[tw] OR disk[tw] OR disc[tw] OR disks[tw] OR discs[tw] OR vertebra*[tw] OR intervertebra*[tw] OR Sacroiliac-joint[mesh] OR Lumbar vertebrae[mesh])

3. Study design: Clinical practice guideline.mp. or practice guideline

Chapter Eight:

Conclusions

8.1 Main findings

This thesis aimed to provide a better understanding of the risk factors and contemporary management of low back pain. Given the relatively poor prognosis and limited effectiveness of treatments for low back pain, understanding factors that influence the risk, prognosis, and treatment for low back pain is essential to reduce disease burden.

The first two studies in this thesis considered risk factors for low back pain. **Chapter Two** summarised the evidence from existing systematic reviews of risk factors for low back pain and/or sciatica. Of the 54 risk factors investigated, 38 risk factors were significantly associated with increased risk of low back pain and/or sciatica and the odds ratios ranged from 1.26 to 13.00. Adverse risk factors included characteristics of the individual (e.g. older age), poor general health (e.g. smoking), physical stress on spine (e.g. vibration) and psychological stress (e.g. depression). **Chapter Three** investigated the extent to which patients can nominate what has triggered their new episode of sudden onset, acute low back pain.

Chapter Three provided evidence that patients can accurately nominate an activity that triggered their sudden onset, acute low back pain. The odds ratios for exposure to patient-nominated risk factors ranged from 8.60 to 30.00 signifying that exposure increases the risk of low back pain. Patients' understanding of risk factors nevertheless seems incomplete as there was evidence that while some of the standard risk factors were well recognised (such as lifting heavy loads); others (such as being distracted during manual tasks) were under-recognised as possible risk factors of an episode of low back pain.

The next study of this thesis **(Chapter Four)** was related to the course, risk and prognosis of low back pain in older men. Specifically, it examined if comorbidities or lifestyle factors could predict the course of existing low back pain or increase the risk of developing low back pain in older men. This chapter showed the odds of persistent pain at 24 months increased with each additional alcoholic drink/week and each additional unit of BMI, but reduced for men who speak English at home. In older men free of low back pain at baseline, the presence of comorbidity increased risk of developing low back pain. These results demonstrated the influence of lifestyle factors and comorbidities on low back pain in older men and suggested that the consideration of these issues in management may improve outcomes.

Chapter Five investigated the effect of Back School on pain and disability for adults with chronic non-specific low back pain in a Cochrane systematic review. Based on 30 trials (4105 participants), the chapter showed that due to the low- to very low-quality of the evidence for all treatment comparisons, outcomes, and follow-up periods investigated, it is uncertain if Back School is effective for chronic low back pain. Although the quality of the evidence was mostly very low, the results showed no difference or a trivial effect in favour of Back School.

The last studies in this thesis were related to vertebral fracture. **Chapter Six** appraised the recommendations and methodological quality of international clinical guidelines[1,2,3,4] for the management of vertebral compression fractures. The results revealed that the clinical guidelines for the management of vertebral compression fracture were inconsistent on diagnostic and therapeutic recommendations. The evidence available to guideline developers was limited in quantity and quality. **Chapter**

Seven described the evolution of guideline-endorsed red flags for vertebral fracture in patients presenting with low back pain and described the consistency between guidelines in the endorsement of red flags for fracture. Eleven discrete red flags were reported in a total of 75 guidelines. The red flags most commonly referred in the guidelines over the years were older age (75%), use of steroids (64%), trauma (57%) and osteoporosis (42%). The red flags that were less frequently reported were night pain (4%) and previous fracture (5%). However, the results revealed that the consistency between guidelines was only fair. The number of red flags endorsed in guidelines to screen for fracture has risen over the years.

8.2. Implications and directions for future research

Collectively, the studies in **Chapters Two** and **Three** provide important findings on risk factors for low back pain and sciatica. A better understanding of risk factors (reported in **Chapter Two**) for low back pain and sciatica by patients and clinicians provides a logical rationale for the development of more effective prevention strategies. For instance, the risk factor identified by the patients (e.g., exposure to manual tasks involving heavy loads, live people or animals, and awkward postures) in **Chapter Three** are likely to be modifiable and therefore potential targets for prevention interventions.

In **Chapter Three** patients nominated risk factors, which had been found in **Chapter Two**, suggesting that patients' perceptions are well aligned with the evidence. However, there were a few risk factors rarely endorsed by patients as risk factors. Clinicians could use this information to advise patients about potential risk factors to avoid and to reduce the risk of developing low back pain. Monitoring exposure to these risk factors could

help not only to avoid cases of low back pain but also those that become persistent, which are often related to the highest burden of this condition.

It is possible that other factors not included in these chapters may also increase the risk for developing of persistent low back pain. Looking for a different set of risk factors would be an important extension of the research in this thesis. Future studies should investigate risk factors for exacerbations (or remissions) of persistent low back pain. The most important direction for future research would be to investigate if this novel information on risk factors can be used to develop effective prevention strategies for low back pain.

According to **Chapter Four,** the number of comorbidities is associated with increased risk of developing low back pain among older men. Furthermore, in those with low back pain, higher alcohol consumption and higher BMI seem to be associated with worse prognosis. Such information is important for patient education/management and could help better inform healthcare professionals about potential factors that may affect the course of the condition in older men.

Although **Chapter Four** collected information on the back complaints of older adults, several questions remain unanswered. First, the results of **Chapter Four** are based upon a community-dwelling sample and may not be applicable to older people with low back pain in residential care. Second, only men were recruited and the extent to which these findings also apply to women is unclear. And finally, results found few predictors with small/ marginal effects. Also, it is important to acquire information on the different aspects of back pain in older adults and compare these with the results from younger adult back pain population. And finally, further research is required to focus on the

opportunity to identify patients at high risk of poor (or good) outcome entering a rehabilitation setting.

Despite the fact that exercise therapy is a common treatment for chronic non-specific low back pain, most of the studies evaluating different types of exercise report similar findings, small effect sizes compared with minimal interventions and often no difference when compared to other exercises, and Back Schools do not seem an exception[5-7]. **Chapter Five** revealed that it is uncertain if Back Schools are effective for chronic low back pain. The quality of the evidence for Back Schools was mostly very low, the results showed no difference or a trivial effect in favour of Back Schools. The low quality of the evidence prevents firm conclusions regarding implications for practice. Another important aspect is that there are myriad potential variants on the Back Schools[8-10] approach regarding the employment of different exercises and educational methods. While the current evidence does not warrant their use, future variations on Back School may have different effects and will need to be studied in future randomized clinical trials and reviews.

The study presented in **Chapter Six** showed that diagnostic and therapeutic recommendations on the management of vertebral fracture in the guidelines[1,2,3,4] were generally inconsistent and none of the clinical guidelines was of overall satisfactory quality. Also, the evidence available to guideline developers was limited in quantity and quality. For instance, in only one guideline[1] included in **Chapter Six**, the recommendations were directly linked to the supporting evidence. This may explain the inconsistency between the recommendations and the supporting evidence. Despite the fact that the recognition of a vertebral fracture may dramatically alter the risk

categorisation of a patient and the management required to prevent future fractures, the consequences of vertebral fracture may have been considerably underestimated by researchers and clinicians.

The most important direction for future research for vertebral fracture would be a systematic literature search performed during guideline development. The majority of guidelines contained recommendations based on consensus of the respective guideline committee. This may explain the inconsistency between the recommendations and the supporting evidence. The future studies should conduct randomised, blinded, controlled trials to determine which treatments are efficacious and safe for patients with this condition. This seems particularly justified for conservative and intervention care, as the results of existing trials did not confirm the best approach in patients with vertebral fracture and there seems to be a reasonable chance that new, high-quality trials will clarify this uncertainty.

Chapter Seven revealed that most of the guidelines[11-18] do not endorse the same set of red flags and that the recommendations for further diagnostic work-up vary between them. An important extension of this research would be to identify the rationale for endorsed red flags and investigate the diagnostic work-up of red flags endorsed in the various guidelines. In addition, an important direction for future research would be to evaluate a combination of red flags in identifying patients with a higher likelihood of serious pathology. Regarding the recommendations on diagnostic procedures to confirm suspected vertebral fracture, it would be important to determine the costs, benefits, and consequences associated with managing patients presenting with suspicion of fracture by close clinical follow-up rather than an immediate referral for imaging. This may help provide a better direction for future guideline recommendations. Finally, it would be

important to revise current recommendations about the use of red flags and also to consider focusing on a smaller subset of red flags specific for fracture. This new approach would be more appropriate than the current indiscriminate endorsement of red flags that appears in most guidelines for managing low back pain.

Concluding Remarks

i) Individual, biomechanical and psychosocial factors increase risk for a future episode of low back pain and sciatica.

ii) Patients can accurately nominate an activity that triggered their sudden-onset acute low back pain.

iii) Low back pain is typically persistent in older men and higher number of comorbidities increased the odds of developing low back pain and lifestyle factors such as higher BMI and higher consumption of alcohol influenced its course.

iv) Back School showed no difference or a trivial effect for chronic low back pain regardless of the comparison used.

v) Recommendations in clinical practice guidelines on vertebral compression fractures interventions should be reviewed.

vi) The number of red flags endorsed in guidelines to screen for fracture has risen over the years; most guidelines do not endorse the same set of red flags.

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Appendix A

A meta-review of systematic reviews of risk factors for low back pain

Patricia Parreira, Chris Maher, Daniel Steffens, Mark Hancock, Manuela Ferreira

Citation

Patricia Parreira, Chris Maher, Daniel Steffens, Mark Hancock, Manuela Ferreira. A meta-review of systematic reviews of risk factors for low back pain. PROSPERO 2016 CRD42016036221
Available from: http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42016036221

Review question

1. What are the risk factors for low back pain (LBP) assessed in systematic reviews and meta-analyses?
2. What is the overall strength of association between each risk factor and LBP based on evidence from systematic reviews and meta-analyses?

Searches

A systematic literature search will be conducted in AMED, MEDLINE, EMBASE, PubMed PsycINFO, SPORTDiscus, and CINHAL databases, using keywords, MeSH and other index terms, as well as combinations of these terms and appropriate synonyms.
There will be no restrictions on date of publication and language. In addition to the electronic database search, we will conduct citation tracking (checking the reference lists of all included studies) for additional relevant articles.

Types of study to be included

We will include the most recent systematic reviews and meta-analyses published in the last 5 years (2011-2016) examining any risk factor for LBP. For a review to be considered systematic, the authors must have defined a strategy to:(i) search for studies,(ii) appraise studies and(iii) synthesise studies.

Condition or domain being studied

Risk factors for low back pain.

Participants/population

Potentially eligible studies will be systematic reviews that examine risk factors for future low back pain. No restrictions will be applied regarding the age or sex of participants. Non-English reviews will be included when translation resources are available.
Excluded will be editorials, correspondence, abstracts, and review summaries.

Intervention(s), exposure(s)

Exposure to risk factors for low back pain

Comparator(s)/control

Not applicable

Primary outcome(s)

Incident cases of low back pain

Secondary outcome(s)

1. Work absence due to an episode of LBP
2. Care seeking for an episode of LBP
3. A disabling episode of LBP

Data extraction (selection and coding)

Two reviewers will independently screen titles and abstracts and then, if necessary, the full text of the studies

identified by the search strategy using an electronic screening form designed to assess eligibility criteria. A reason for exclusion will be provided for the exclusion of all full-text papers screened.
We will extract study-specific relative risk estimates (risk ratio, odds ratio, hazard ratio, or incident risk ratio, as reported by the authors of the meta-analysis) from the least biased review (see below) published in the past 5 years.

Risk of bias (quality) assessment
All included systematic reviews and meta-analyses will be evaluated using the PRISMA checklist and AMSTAR assessment tools (revised version of A Measurement Tool to Assess Systematic Reviews). The AMSTAR tool will be applied to each systematic review independently by each reviewer. Any disagreements will be resolved by discussion.

Strategy for data synthesis
The characteristics of all the systematic reviews will be summarized descriptively. Evidence tables will be produced to synthesize the clinical findings and recommendations of the least biased systematic review considering each risk factor.

Analysis of subgroups or subsets
None planned.

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Anticipated or actual start date
09 March 2016

Anticipated completion date
09 June 2028

Funding sources/sponsors
Professor Chris Maher is funded by a Fellowship from the National Health and Medical Research Council of Australia.
Manuela Ferreira holds a Sydney Medical Foundation Fellowship.
Mark Hancock
Patricia Parreira is funded by CAPES, an agency under The Ministry of Education of Brazil.

Conflicts of interest
None known

Language

English

Country
Australia

Stage of review
Review_Ongoing

Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Humans; Low Back Pain; Research Design; Risk Factors

Date of registration in PROSPERO
09 March 2016

Date of publication of this version
09 March 2016

Revision note for this version
I have antecipated my completion date

Details of any existing review of the same topic by the same authors

Stage of review at time of this submission

Stage	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	Yes	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Revision note
I have antecipated my completion date

Versions
09 March 2016

Appendix B

Cochrane Library

Cochrane Database of Systematic Reviews

Back schools for chronic non-specific low back pain (Protocol)

Parreira P, Heymans MW, van Tulder MW, Esmail R, Koes BW, Poquet N, Lin CWC, Maher CG

Parreira P, Heymans MW, van Tulder MW, Esmail R, Koes BW, Poquet N, Lin CWC, Maher CG.
Back schools for chronic non-specific low back pain.
Cochrane Database of Systematic Reviews 2015, Issue 5. Art. No.: CD011674.
DOI: 10.1002/14651858.CD011674.

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[Intervention Protocol]

Back schools for chronic non-specific low back pain

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Editorial group: Cochrane Back and Neck Group.
Publication status and date: New, published in Issue 5, 2015.

Citation: Parreira P, Heymans MW, van Tulder MW, Esmail R, Koes BW, Poquet N, Lin CWC, Maher CG. Back schools for chronic non-specific low back pain. *Cochrane Database of Systematic Reviews* 2015, Issue 5. Art. No.: CD011674. DOI: 10.1002/14651858.CD011674.

ABSTRACT

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

The objective of this systematic review will be to determine the effect of back schools on pain and disability for people with chronic non-specific low back pain. We will also examine the effect of low back pain on work status in trials that solely recruit workers.

BACKGROUND

Description of the condition

Low back pain is a major problem worldwide and is associated with enormous socio-economic and health costs to society (van Tulder 2006). Estimates suggest that in European countries the direct and indirect costs of low back pain range from 2 billion to 4 billion euros annually (van Tulder 2006). In Australia, the costs associated with low back pain exceed AUS 1 billion/ yearly; in the United States they were estimated at more than USD 50 billion per year (Dagenais 2008,Walker 2003;Deyo 1998). Although low back pain rarely indicates a serious underlying disorder, people with low back pain that lasts for longer than one or two months have an increased risk of developing longer-term disability and repeated care-seeking (Waddell 1987). Moreover, the recovery process of people with chronic low back pain is slow, and their demands on the healthcare system are both large and costly (Henschke 2008). To date, several treatments are available for people with chronic low back pain. However, these treatments have a moderate effect (Airaksinen 2006; Delitto 2011). Furthermore, there are still discrepancies between countries in clinical guidelines and therapeutic recommendations for people with low back pain (Koes 2001; Staal 2003; Waddell 2001). Systematically summarising the literature as new trials are published provides the best current evidence for the treatment of (subgroups of) people with low back pain.

Description of the intervention

The original Swedish Back School was introduced by Zachrisson-Forsell in 1969. It was meant to reduce the pain and prevent recurrences of episodes of low back pain (Zachrisson-Forsell 1980; Zachrisson-Forsell 1981). The Back School consisted of information on the anatomy of the back, biomechanics, optimal posture, ergonomics, and back exercises. The aim was to reduce back pain and teach people to care for their own backs and back pain in an active way, should back pain recur.

How the intervention might work

The original Back School scheduled four small group sessions during a 2-week period, each session lasting 45 minutes. Since the introduction of the Swedish Back School, the content and length of back schools have changed and today appear to vary widely. For example, there are back schools with a single 4-hour outpatient treatment session (Berwick 1989); 3 to 21 outpatient treatment sessions of 45 to 90 minutes each (Donchin 1990; Glomsrød 2001; Hurri 1989; Indahl 1995; Indahl 1998; Leclaire 1996; Lønn 1999; Penttinen 2002); and 3 to 5 weeks of inpatient programs that run for 8 hours a day (Härkäpää 1989; Härkäpää 1990; Linton 1989). These back school interventions seem to use a variety of methods, although they all share the same content as the original back school and combine information about back pain with exercises.

Why it is important to do this review

This review is an update of a previously conducted Cochrane review of randomised controlled trials (RCTs) on the effectiveness of back schools, Heymans 2004, and two systematic reviews on back schools and group education interventions for low back pain, Cohen 1994 and Koes 1994. We split the Cochrane review that was published in 2004 into two reviews. In this review, we will present the results on the effectiveness of back schools for chronic non-specific low back pain. It was not possible to statistically pool the studies in the previous reviews because of the heterogeneity of included studies. Conclusions were generated on the basis of the methodological quality scores of the studies, assessed using a generally accepted criteria list, in combination with a best evidence synthesis (van Tulder 2003). Other studies included a mix of acute and subacute patients and found positive, in Indahl 1995 and Indahl 1998, or no effects of low-intensity back schools on sick leave (Leclaire 1996). It was concluded that a modified, intensive Swedish Back School offered in an occupational setting seemed to be the most effective type of back school for reducing the intensity and recurrence of low back pain. Since 2004, a number of new RCTs have been published that evaluate the effectiveness of back schools, and The Cochrane Collaboration has published updated method guidelines for Cochrane reviews, in Higgins 2011, and in the field of back pain, in Furlan 2009.

OBJECTIVES

The objective of this systematic review will be to determine the effect of back schools on pain and disability for people with chronic non-specific low back pain. We will also examine the effect of low back pain on work status in trials that solely recruit workers.

METHODS

Criteria for considering studies for this review

Types of studies

We will include only RCTs and quasi-RCTs.

Types of participants

We will include studies that examine participants with chronic (more than 12 weeks duration) non-specific low back pain, aged 18 to 70 years. We will define low back pain as pain localised below the scapulae and above the cleft of the buttocks; non-specific indicates that no specific cause was detected such as infection, neoplasm, metastasis, osteoporosis, rheumatoid arthritis, fracture, or inflammatory process. We will also exclude low back pain due to pregnancy.

Types of interventions

We will include studies in which one of the treatments consists of a back school type of intervention. A back school is defined as an educational and skills acquisition program, including exercises,addressed to groups of patients who are supervised by a healthcare provider (Zachrisson-Forsell 1980). This back school review is therefore different from other low back pain Cochrane reviews about exercise (Hayden 2005), patient education (Engers 2008), and multidisciplinary rehabilitation (Karjalainen 2003). We will include trials that use a clear contrast for the back school intervention, such as usual care, waiting list, or other interventions such as exercise therapy or manipulation. We will allow additional interventions. However, if the back school is part of a larger multidisciplinary treatment program, we will include the study only if a contrast exists for the back school. For example, we will include a study that compares a back school plus a fitness program against a fitness program, but we will not include a study that compares a back school plus a fitness program against a waiting list. We will not include trials that study the effectiveness of back schools in workers or non-workers without low back pain at study onset because these are aimed primarily at the prevention of low back pain.

Types of outcome measures

We will consider trials that include at least one of the following outcomes:

1. pain
2. disability
3. work status

We will include trials that report outcomes for short-term (three months or less), intermediate-term (three to six months), and long-term (more than six months) follow-up.

Primary outcomes

We will consider the following primary outcomes:

1. pain (e.g. measured by visual analogue scale or numerical rating scale)
2. disability (e.g. measured by Oswestry Disability Index or Roland-Morris Disability Questionnaire)

Secondary outcomes

We will consider the following secondary outcomes:

1. work status in trials that solely recruit workers (e.g. days of sick leave)
2. adverse events

Search methods for identification of studies

We will use the search methods developed by the Cochrane Back Review Group in Furlan 2009 and Chapter 6 Searching for Studies of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). The Trials Search Co-ordinator of the Back Review Group will develop the search strategies.

For this update, we will search for trials in the Cochrane Back Review Group Trials Register, the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE (OvidSP), MEDLINE In-Process & Other Non-Indexed Citations (OvidSP), and EMBASE (OvidSP) from 2004 to current. We have added CINAHL (EBSCO), PsycINFO (OvidSP), and the clinical trials registries ClinicalTrials.gov and the World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) and will search from inception to current.

Searches of these databases were conducted in 2007, 2009, 2011, and 2014. See Appendix 1 for the 2014 strategy and any changes to this strategy for the period of this update.

We will also screen references listed in the reference lists of relevant reviews and included studies, and consult experts in the field of low back pain management to identify potentially relevant studies we might have missed.

Data collection and analysis

For each of the steps, two review authors will independently select new studies, assess the risk of bias, and extract data (using a standardised form). Any differences will be resolved by consensus, with a third review author brought in if disagreements persist.

Selection of studies

For this update, we will first reassess the included studies from the original review to ensure they meet our revised inclusion criteria. The Trials Search Co-ordinator from the Cochrane Back Review Group will update the literature search. Following the same process as in the original and updated review, two review authors will first screen the titles and abstracts of the new studies. We will retrieve the full text of all potentially relevant studies for final selection of eligible studies.

Data extraction and management

Two review authors will independently extract the data using pre-standardised data extraction forms. We will collect the following information:

1. population characteristics (participant population source or setting, study inclusion criteria, duration of low back pain episode);
2. intervention characteristics (description and type of back school, duration and number of treatment sessions, intervention delivery type, and cointerventions); and
3. outcome data (pain intensity, disability, work status, adverse events).

When several time points fall within the same category, we will use the time point closest to 6 weeks for the short term, 4 months for the intermediate term, and 12 months for the long term.

Assessment of risk of bias in included studies

Two review authors will independently assess the risk of bias in included studies. We will employ a consensus method to resolve disagreements and consult a third review author if disagreement persists. If an article does not contain information on (one or more of) the criteria, we will contact the authors for additional information. We anticipate that authors might work at places other than those listed in the publications, in which case we will try to locate their current working address through their last publication in MEDLINE. If we are unable to find a current working address, we will send the request for information to the address listed on the paper we will include in our review. If we cannot contact the authors or if the information is no longer available, we will score the criteria as 'unclear'.

We will follow the Cochrane Back Review Group's guidance on assessing the risk of bias (Furlan 2009). We have listed the assessment criteria for each type of bias along with the operational definitions in Appendix 2.

Measures of treatment effect

We will evaluate clinical homogeneity of studies by exploring their similarities and differences, taking into consideration the study population, type of back school and reference treatments, timing of follow-up measurements and outcomes, and measurement instruments. We will formally test for statistical homogeneity for studies that are sufficiently clinically homogenous to pool. On the basis of these evaluations, we will attempt to statistically pool the data for the outcome measures (pain, disability, and work status), recognising that there may be insufficient data to accomplish this. We will meta-analyse data according to the follow-up period (short-, intermediate-, and long-term follow-up).

We will present the results of each RCT as point estimates with corresponding 95% confidence intervals. As per the guidelines of the Editorial Board of the Cochrane Back Review Group, we will analyse results by presenting the overall quality of the evidence using the adapted Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach for each outcome (Furlan 2009). For comparisons where studies are too heterogeneous, we will not perform a meta-analysis. In situations where only one study measures the outcome, we will consider the data to be 'sparse' and will label the evidence as 'low quality'.

Data synthesis

We will assess the overall quality of the evidence for each outcome by using the GRADE approach, as recommended by the Cochrane Back Review Group in Furlan 2009 and the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) Following GRADE guidelines, we will categorise the final grade for quality of evidence for each subquestion as high, moderate, low, or very low. We will grade the evidence available to answer each subquestion on the following domains, which are further discussed in Appendix 3 of this protocol: study design, risk of bias, inconsistency, indirectness, imprecision, publication bias, magnitude of the effect, dose-response gradient, and influence of all plausible residual confounding, and based on Furlan 2014.

Subgroup analysis and investigation of heterogeneity

We will pursue subgroup analyses to determine if the estimates of effect are different in studies of back schools that 1) include participants with low back pain with radiation versus low back pain without radiation, and 2) are conducted in an occupational versus another setting.

Sensitivity analysis

We will perform sensitivity analyses to see if the overall results on effectiveness between comparison groups change when different definitions of high risk of bias are used, that is if high risk of bias is defined as fulfilling five or more or seven or more criteria, or as having an adequate concealment of treatment allocation.

ACKNOWLEDGEMENTS

We thank professor Dr. L. M. Bouter for his insightful suggestions for the original review. This protocol is based on the protocol for acute low back pain (Heymans 2004).

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Search strategies

MEDLINE

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. comparative study.pt.
4. clinical trial.pt.
5. pragmatic clinical trial.pt.
6. randomized.ab.
7. placebo.ab,ti.
8. drug therapy.fs.
9. randomly.ab,ti.
10. trial.ab,ti.
11. groups.ab,ti.
12. or/1-11
13. (animals not (humans and animals)).sh.
14. 12 not 13

15. dorsalgia.ti,ab.
16. exp Back Pain/
17. backache.ti,ab.
18. (lumbar adj pain).ti,ab.
19. coccyx.ti,ab.
20. coccydynia.ti,ab.
21. sciatica.ti,ab.
22. exp sciatic neuropathy/
23. spondylosis.ti,ab.
24. lumbago.ti,ab.
25. back disorder$.ti,ab.
26. exp Back Muscles/
27. or/15-26
28. back school.mp.
29. 14 and 27 and 28
30. limit 29 to yr="2011-2014"
31. limit 29 to ed=20110601-20140304
32. 30 or 31

The June 2011 search used a different entry date filter to current strategy:

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. exp Low Back Pain/
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. or/12-22
24. back school.mp.
25. 11 and 24 and 23
26. limit 25 to yr="2009 - 2011"
27. 2009$.ed.
28. 2010$.ed.
29. 2011$.ed.
30. 27 or 28 or 29
31. 25 and 30
32. 26 or 31

The 26 April 2007 strategy used a different study design filter to current 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. back school.mp.
26. 12 and 24 and 25
27. limit 26 to yr="2004 - 2007"

EMBASE

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$)).mp.
28. trial.mp.
29. (versus or vs).mp.
30. or/15-29
31. 14 or 30
32. exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/
33. human/ or normal human/ or human cell/
34. 32 and 33
35. 32 not 34
36. 31 not 35
37. dorsalgia.mp.
38. back pain.mp.
39. exp BACKACHE/
40. (lumbar adj pain).mp.
41. coccyx.mp.
42. coccydynia.mp.
43. sciatica.mp.
44. ischialgia/
45. spondylosis.mp.
46. lumbago.mp.
47. back disorder$.ti,ab.
48. or/37-47
49. back school.mp.
50. 36 and 48 and 49
51. limit 50 to yr=2011-2014
52. limit 50 to em=201123-201409
53. 51 or 52

The June 2011 strategy used a different animal study and entry date filter:

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$)).mp.
28. trial.mp.
29. (versus or vs).mp.
30. or/15-29
31. 14 and 30
32. human/
33. Nonhuman/
34. exp ANIMAL/
35. Animal Experiment/
36. 33 or 34 or 35
37. 32 not 36
38. 31 not 36
39. 37 and 38
40. 38 or 39
41. dorsalgia.mp.
42. back pain.mp.
43. exp BACKACHE/
44. (lumbar adj pain).mp.
45. coccyx.mp.
46. coccydynia.mp.
47. sciatica.mp.
48. exp ISCHIALGIA/
49. spondylosis.mp.
50. lumbago.mp.
51. exp Low back pain/
52. or/41-51
53. back school.mp.
54. 40 and 52 and 53
55. limit 54 to yr="2009 - 2011"
56. 2009$.em.
57. 2010$.em.
58. 2011$.em.
59. 56 or 57 or 58
60. 54 and 59
61. 55 or 60

CENTRAL

The CENTRAL strategy was updated in June 2011:
#1 MeSH descriptor: [Back Pain] explode all trees
#2 dorsalgia
#3 backache
#4 (lumbar near pain) or (coccyx) or (coccydynia) or (sciatica) or (spondylosis)
#5 MeSH descriptor: [Sciatica] explode all trees
#6 MeSH descriptor: [Spine] explode all trees
#7 MeSH descriptor: [Spinal Diseases] explode all trees
#8 (lumbago) or (discitis) or (disc near degeneration) or (disc near prolapse) or (disc near herniation)
#9 spinal fusion
#10 facet near joints
#11 MeSH descriptor: [Intervertebral Disc] explode all trees

#12 postlaminectomy
#13 arachnoiditis
#14 failed near back
#15 MeSH descriptor: [Cauda Equina] explode all trees
#16 lumbar near vertebra*
#17 spinal near stenosis
#18 slipped near (disc* or disk*)
#19 degenerat* near (disc* or disk*)
#20 stenosis near (spine or root or spinal)
#21 displace* near (disc* or disk*)
#22 prolap* near (disc* or disk*)
#23 (#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)
#24 "back school"
#25 (#23 and #24)
#26 #25 from 2011 to 2014, in Trials
The January 30, 2009 search used the following strategy:
#1 MeSH descriptor Back explode all trees
#2 MeSH descriptor Buttocks, this term only
#3 MeSH descriptor Leg, this term only
#4 MeSH descriptor Back Pain explode tree 1
#5 MeSH descriptor Back Injuries explode all trees
#6 MeSH descriptor Low Back Pain, this term only
#7 MeSH descriptor Sciatica, this term only
#8 (low next back next pain)
#9 (lbp)
#10 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9)
#11 (back school):ti,ab,kw
#12 (#10 AND #11), from 2007 to 2009

CINAHL

The entry date filter (line S46) was not used in previous strategies.
S47 S45 OR S46
S46 S44 and EM 20110601-20140304
S45 S42 AND S43 Limiters - Published Date: 20110601-20140331
S44 S42 AND S43
S43 back school
S42 S24 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
S40 lumbago
S39 (MH "Spondylolysis")
S38 (MH "Spondylolisthesis")
S37 lumbar N2 vertebrae
S36 (MH "Lumbar Vertebrae")
S35 back disorder*
S34 coccydynia
S33 coccyx
S32 sciatica
S31 (MH "Sciatica")
S30 (MH "Coccyx")
S29 lumbar N5 pain
S28 lumbar W1 pain

S27 backache
S26 (MH "Back Pain+")
S25 dorsalgia
S24 S22 not S23
S23 (MH "Animals+")
S22 S21 or 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 S7 or S6 or S5 or S4 or S3 or S2 or S1
S21 volunteer*
S20 prospectiv*
S19 control*
S18 followup stud*
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 W3 trial
S2 randomi?ed controlled trial*
S1 (MH "Clinical Trials+")
For the June 2011 search, Line S3 was changed from "clinical W8 trial" to "clinical W3 trial" and line S21 and S42 were added:
S51 S49 and S50 Limiters - Published Date from: 20090101-20111231
S50 "back school"
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

1 clinical trials/
2 controlled trial.mp.
3 RCT.mp.
4 (Random* adj3 trial).mp.
5 (clin* adj3 trial).mp.
6 (sing* adj2 blind*).mp.
7 (doub* adj2 blind*).mp.
8 placebo.mp. or exp Placebo/
9 latin square.mp.
10 (random* adj2 assign*).mp.
11 prospective studies/
12 (prospective adj stud*).mp.
13 (comparative adj stud*).mp.
14 treatment effectiveness evaluation/
15 (evaluation adj stud*).mp.
16 exp Posttreatment Followup/
17 follow?up stud*.mp.
18 or/1-17
19 back pain/
20 lumbar spinal cord/
21 (low adj back adj pain).mp.
22 (back adj pain).mp.
23 spinal column/

24 (lumbar adj2 vertebra*).mp.
25 coccyx.mp.
26 sciatica.mp.
27 lumbago.mp.
28 dorsalgia.mp.
29 back disorder*.mp.
30 "back (anatomy)"/
31 ((disc or disk) adj degenerat*).mp.
32 ((disc or disk) adj herniat*).mp.
33 ((disc or disk) adj prolapse*).mp.
34 (failed adj back).mp.
35 or/19-34
36 back school.mp.
37 18 and 35 and 36
38 limit 37 to yr=2011-2014
The 15 June 2011 search used a different strategy and was conducted in Cambridge Scientific Abstracts, the service provider at the time.
((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)
OR DE=(neck))) and(KW=(back school))

ClinicalTrials.gov and WHO ICTRP

Basic search: "back school" and back pain
In June 2011, the initial searches were conducted in different fields
Condition: back pain
AND
Intervention: back school

Appendix 2. 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 (for example a list of random numbers); assignment envelopes were used without appropriate safeguards (for example 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 participant-reported outcomes in which the participant 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 participants and care providers (e.g. cointerventions, 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 dropouts are very large, imputation using even 'acceptable' methods may still suggest a high risk of bias) (van Tulder 2003). The percentage of withdrawals and dropouts 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 (for example subscales) that were not pre-specified; one or more 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 were reported incompletely so that they cannot be entered in a meta-analysis; 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, percentage of participants with neurological symptoms) (van Tulder 2003).

Cointerventions (performance bias)

Bias because cointerventions were different across groups

There is low risk of bias if there were no cointerventions 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 intervention(s). For single-session interventions (for example surgery), this item is irrelevant (van Tulder 2003).

Intention-to-treat-analysis

There is low risk of bias if all randomised participants 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

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

Appendix 3. The GRADE approach to evidence synthesis

We will categorise the quality of evidence as follows:

- High: Further research is very unlikely to change either the estimate or confidence in the results.
- Moderate: Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.
- Low: Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.
- Very low: Any estimate of effect is very uncertain.

We will grade the evidence available to answer each subquestion on the domains in the following manner:

1. Study design

2. Risk of bias

Limitations in the study design and implementation may bias the estimates of the treatment effect. If studies suffer from any major limitation, the accuracy in the estimate of the effect and its recommendation can be affected. We will examine all studies on five types of biases:

a) Selection (random sequence generation, allocation concealment, group similarities at baseline): We will score this item as low risk of bias if two or more of these items are defined as having low risk.
b) Performance (blinding of participants, blinding of healthcare providers, cointerventions, and compliance with intervention): We will score this item as low risk of bias if three or more of these items are defined as having low risk.
c) Attrition (dropouts and intention-to-treat analysis): We will score this item as low risk of bias if both of these items are defined as having low risk.
d) Measurement (blinding of the outcome assessors and timing of outcome assessment): We will score this item as low risk of bias if both of these items are defined as having low risk.
e) Reporting bias (selective reporting): We will score this item as low risk of bias if it is defined as having low risk.
We will define a study with a low risk of bias as having low risk of bias on four or more of these items.

3. Inconsistency

Inconsistency refers to an unexplained heterogeneity of results. Widely differing estimates of the treatment effect (that is heterogeneity or variability in results) across studies suggest true differences in underlying treatment effect. Inconsistency may arise from differences in populations (for example drugs may have larger relative effects in sicker populations), interventions (for example larger effects with higher drug doses), or outcomes (for example diminishing treatment effect with time). We will downgrade the quality of evidence as follows:

• by one level: when the heterogeneity or variability in results is large (for example I^2 above 80%)

• by two levels: when the heterogeneity or variability in results is large AND there was inconsistency arising from populations, interventions, or outcomes

4. Indirectness

Indirect population, intervention, comparator, or outcome; the question being addressed in this systematic review is different from the available evidence regarding the population, intervention, comparator, or an outcome in the included randomised trial. We will downgrade the quality of evidence as follows:

• by one level: when there is indirectness in only one area

• by two levels: when there is indirectness in two or more areas

5. Imprecision

Results are imprecise when studies include relatively few participants and events and thus have wide confidence intervals around the estimate of the effect. In such cases we judge the quality of the evidence as lower than it otherwise would have been because of resulting uncertainty in the results. We consider each outcome separately.

For dichotomous outcomes

We will consider imprecision for either of the following two reasons:

1. There is only one study. When there is more than one study, the total number of events is less than 300 (a threshold rule-of-thumb value) (Mueller 2007).

2. 95% confidence interval around the pooled or best estimate of effect includes both a) no effect and b) appreciable benefit or appreciable harm. The threshold for 'appreciable benefit' or 'appreciable harm' is a relative risk reduction or relative risk increase greater than 25%.

We will downgrade the quality of the evidence as follows:

• by one level: when there is imprecision due to (1) or (2)

• by two levels: when there is imprecision due to (1) and (2)

For continuous outcomes

We will consider imprecision for either of the following two reasons:

1. There is only one study. When there is more than one study, 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 deviation, representing a small effect).

2. 95% confidence interval includes no effect and the upper or lower confidence limit crosses an effect size (standardised mean difference) of 0.5 in either direction.

We will downgrade the quality of the evidence as follows:

• by one level: when there is imprecision due to (1) or (2)

• by two levels: when there is imprecision due to (1) and (2)

6. Publication bias

Publication bias is a systematic underestimate or an overestimate of the underlying beneficial or harmful effect due to the selective publication of studies. We will downgrade the quality of evidence as follows:

• by one level: when the funnel plot suggests publication bias

7. Magnitude of the effect

8. Dose-response gradient

9. Influence of all plausible residual confounding

CONTRIBUTIONS OF AUTHORS

Rosmin Esmail and Maurits van Tulder conducted the study selection, quality assessment, data extraction, and analysis of all studies included in the original (1999) review. Martijn W Heymans and Maurits van Tulder updated the original review for new trials and conducted the study selection, quality assessment, data extraction, and analysis of all new studies for the second (2004) version of the review. All review authors were involved in developing the protocol for this third version of the review and will be involved in writing the final manuscript.

DECLARATIONS OF INTEREST

Two review authors (Christopher Maher and Maurits van Tulder) are on the Editorial Board of the Cochrane Back Review Group. Editors are required to conduct at least one Cochrane review, which ensures that editors are aware of the processes and commitment needed to conduct reviews.

SOURCES OF SUPPORT

Internal sources

- VU University Medical Center, Netherlands.
- Christopher Maher is funded by National Health and Medical Research Council, Australia.
- Patricia Parreira is funded by Coordenação de Aperfeiçoamento de Pessoal de Nível Superior, Brazil.
- Chung-Wei Christine Lin is funded by a Career Development Fellowship from the National Health and Medical Research Council, Australia.

External sources

- VU University Medical Center, Netherlands.
- The George Institute for Global Health, Sydney Medical School, The University of Sydney, Australia.

Appendix C

PROSPERO International prospective register of systematic reviews

An overview of clinical guidelines for the management of vertebral compression fracture

Patricia Parreira, Chris Maher, Manuela Ferreira

Citation

Patricia Parreira, Chris Maher, Manuela Ferreira. An overview of clinical guidelines for the management of vertebral compression fracture. PROSPERO 2015:CRD42015029343 Available from http://www.crd.york.ac.uk/PROSPERO_REBRANDING/display_record.asp?ID=CRD42015029343

Review question(s)

What is the content of (inter)national clinical guidelines for the management of compression fracture?

Searches

Clinical guidelines will be searched using electronic databases: MEDLINE and PubMed, PEDro, CINAHL, EMBASE electronic databases. We also will search in guideline databases, including the National Guideline Clearinghouse, Canadian Medical Association InfoBase, Guidelines International Network, National Institute for Clinical Excellence, National Library for Health guidelines database and Scottish Intercollegiate Guidelines Network. We will screen the reference list of relevant guidelines and use Web of Science citation index to identify guidelines citing the previous guideline.

Types of study to be included

We will include guidelines.

Condition or domain being studied

Vertebral compression fracture (VCFs) is the most common type of osteoporotic fracture. VCFs of the thoracic and lumbar spine account for an estimated 700,000 of the 1.5 million osteoporotic fractures occurring annually in the United States. For Europe, their annual incidence has been estimated at 1% for women aged 50 -79 years and at 0.6% for men in the same age category. The presence of a fragility vertebral fracture has several clinical and management implications. Clinical practice guidelines have been created in several countries to help primary care practitioners to provide care that is aligned with the best evidence

The aim of this study will be to present and compare the content of (inter)national clinical guidelines for the management of compression fracture. These guidelines will be compared regarding the content of their recommendations, the target group, the guideline committee and its procedures, and the extent to which the recommendations were based on the available literature (the scientific evidence).

Participants/ population

Studies conducted on female and/or male participants with compression fracture of all age groups will be included.

Intervention(s), exposure(s)

Evidence-based clinical practice guidelines will be included if they satisfy the following criteria:

1. The clinical practice guideline was produced under the auspices of a health professional association or society, public or private organisation, health care organisation or plan, or government agency. A clinical practice guideline developed and issued by an individual or group of individuals not officially sponsored or supported by one of the above types of organisations will not be included.

2. The clinical practice guideline is publicly available.

3. A systematic literature search and review of existing scientific evidence published in peer-reviewed journals was

performed during the guideline development OR the guidelines were based on a systematic review published in the four years preceding publication of the guideline.

4. The clinical practice guideline contains systematically developed statements that include recommendations, strategies, or information to guide decisions about appropriate health care.

Comparator(s)/ control

Evidence-based clinical practice guidelines will be included if they satisfy the following criteria:

1. The clinical practice guideline was produced under the auspices of a health professional association or society, public or private organisation, health care organisation or plan, or government agency. A clinical practice guideline developed and issued by an individual or group of individuals not officially sponsored or supported by one of the above types of organisations will not be included.

2. The clinical practice guideline is publicly available.

3. A systematic literature search and review of existing scientific evidence published in peer-reviewed journals was performed during the guideline development OR the guidelines were based on a systematic review published in the four years preceding publication of the guideline.

4. The clinical practice guideline contains systematically developed statements that include recommendations, strategies, or information to guide decisions about appropriate health care.

Outcome(s)

Primary outcomes

1. Diagnostic recommendations

2. Therapeutic recommendations

Secondary outcomes

none

Data extraction, (selection and coding)

Two reviewers will independently screen titles and abstracts and then, if necessary, the full text of studies identified by the search strategy using an electronic screening form designed to assess eligibility criteria. A reason will be provided for the exclusion of all full-text papers screened.

Risk of bias (quality) assessment

All guidelines will be reviewed independently by two authors and will be scored for methodological quality according to the AGREE II 1 instrument (Appraisal of Guidelines, Research and Evaluation) which has been shown to be reliable for assessment the quality of clinical guidelines. This tool consists of 23 items organised in six domains so that each domain is intended to capture a separate dimension of guideline quality. Each item is rated on a seven-point scale. A score of 7 indicates that the quality of reporting is exceptional and all of the criteria and considerations articulated in the user's manual were met. A score between 2 and 6 indicates that the reporting of the AGREE II item does not fully meet criteria or considerations. As more criteria are met and more considerations addressed, item scores increase.

Strategy for data synthesis

None planned.

Analysis of subgroups or subsets

None planned

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Anticipated or actual start date
17 November 2015

Anticipated completion date
12 June 2018

Funding sources/sponsors
The George Institute/ University of Sydney

Conflicts of interest
None known

Language
English

Country
Australia

Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Bone Diseases, Metabolic; Fractures, Compression; Humans; Spinal Fractures; Vertebroplasty

Stage of review
Ongoing

Date of registration in PROSPERO
09 December 2015

Date of publication of this revision
09 December 2015

Stage of review at time of this submission	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Appendix D

Evolution, and consistency between guidelines, of guideline-endorsed red flags for fracture in patients presenting with LBP

Patricia Parreira, Adrian Traeger, Aron Downie, Mark Hancock, Bart Koes, Chris Maher

Citation

Patricia Parreira, Adrian Traeger, Aron Downie, Mark Hancock, Bart Koes, Chris Maher. Evolution, and consistency between guidelines, of guideline-endorsed red flags for fracture in patients presenting with LBP. PROSPERO 2017 CRD42017065614 Available from: http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017065614

Review question

To describe the evolution of guideline-endorsed red flags for fracture in patients presenting with low-back pain (LBP).
To describe consistency between guidelines in the endorsement of red flags for fracture.

Searches

Low back pain guidelines which endorse red flags for fracture in patients presenting with LBP will be identified by searching MEDLINE and PubMed, PEDro, CINAHL, and EMBASE electronic databases. We will also search in guideline databases, including the National Guideline Clearinghouse and Canadian Medical Association InfoBase. We will screen the reference lists of relevant guidelines and use Web of Science citation index to identify guidelines citing the previous guideline.
There will be no restrictions on date of publication or language.

Types of study to be included

Evidence-based clinical practice guidelines will be included if they satisfy the PEDro criteria for evidence-based clinical practice guidelines (points 1-4 below) and list red flags (point 5):1. The clinical practice guideline was produced under the auspices of a health professional association or society, public or private organisation, health care organisation or plan, or government agency. A clinical practice guideline developed and issued by an individual or group of individuals not officially sponsored or supported by one of the above types of organisations will not be included.2. The clinical practice guideline was publicly available.3. A systematic literature search and review of existing scientific evidence published in peer-reviewed journals was performed during the guideline development OR the guidelines were based on a systematic review published in the four years preceding publication of the guideline.4. The clinical practice guideline contained systematically developed statements that included recommendations, strategies, or information to guide decisions about appropriate health care.5. The guideline lists red flags for fracture. “Red flags” are features from the patient’s medical history and physical examination which are thought to be associated with a higher risk of serious pathology.

Condition or domain being studied

Spinal fracture and malignancy are the most common serious pathologies affecting the spine. In patients with low back pain presenting to primary care, between 1% and 4% will have a spinal fracture and in less than 1% malignancy, whether primary tumour or metastasis, will be the underlying cause. Most clinical practice guidelines for back pain recommend the use of red flags to help identify those patients with a higher likelihood of spinal fracture or malignancy who then become candidates for more extensive diagnostic investigations. There is confusion, however, as the guidelines have produced different lists of red flags to screen for spinal fracture.

Participants/population

Potentially eligible studies will be guidelines that examine red flags for spine fracture. No restrictions will be applied regarding the age or sex of participants. Non-English reviews will be included when translation

resources will be available. Excluded will be editorials, correspondence, abstracts, and review summaries.

Intervention(s), exposure(s)
Not applicable.

Comparator(s)/control
Not applicable.

Primary outcome(s)
Red flags for fracture in patients presenting with LBP.

Secondary outcome(s)
None.

Data extraction (selection and coding)
Two review authors will independently extract the data using pre-standardised data extraction forms. We will present the guidelines in a matrix table. In the columns, we will list the earliest published guideline to the current guideline. Rows will include each discrete red flag for fracture listed in a guideline. The following data will extracted: health professional association or society, year of publication, precise wording of endorsed red flag for fracture, and recommendations for diagnosis.

Risk of bias (quality) assessment
None.

Strategy for data synthesis
We will present the guidelines in a matrix table. In the columns, we will list the earliest published guideline to the current guideline. Rows will include each discrete red flag for fracture listed in a guideline. The following data will extracted: health professional association or society, year of publication, precise wording of endorsed red flag for fracture, and recommendations for diagnosis.

Analysis of subgroups or subsets
None planned.

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None

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Anticipated or actual start date
07 April 2017

Anticipated completion date
09 August 2017

Funding sources/sponsors
Professor Chris Maher is funded by a Fellowship from the National Health and Medical Research Council of Australia.
Patricia Parreira is funded by CAPES, an agency under The Ministry of Education of Brazil

Conflicts of interest
None known

Language
English

Country
Australia

Stage of review
Review_Ongoing

Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Fractures, Bone; Humans; Low Back Pain

Date of registration in PROSPERO
09 May 2017

Date of publication of this version
09 May 2017

Details of any existing review of the same topic by the same authors

Stage of review at time of this submission
The review has not started

Stage	Started	Completed
Preliminary searches	No	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Versions
09 May 2017