

Effectiveness of chiropractic care for low back pain: protocol for an updated systematic review and meta-analysis of randomized trials

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A 2016 review of randomized trials found that chiropractic care was as effective as physiotherapy for low back pain and was unable to establish the effectiveness of chiropractic care vs. exercise therapy or medical care; however, this review had several

Efficacit   des soins chiropratiques dans le traitement de la lombalgie: protocole d'une revue syst  matique actualis  e et d'une m  ta-analyse d'essais randomis  s
Une revue d'essais randomis  s publi  e en 2016 a conclu que les soins chiropratiques   taient aussi

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Conflicts of Interest:

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methodological limitations. We will conduct an updated systematic review to address these limitations and determine the effectiveness of chiropractic care compared to other usual care approaches for adults with non-specific low back pain. We will search for eligible trials indexed in MEDLINE, AMED, Embase, CINAHL, the Index to Chiropractic Literature, and the Cochrane Library from January 1, 2016 through August 31, 2026. Pairs of independent reviewers will conduct study selection, data abstraction, and risk-of-bias assessment. We will conduct meta-analyses using random-effects models and assess the certainty of evidence of all outcomes with the GRADE approach. Our results will be disseminated in a peer-reviewed publication and conference presentations.

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KEY WORDS: chiropractic care; low back pain; systematic review; effectiveness

Introduction

Low back pain (LBP) is a common condition and a leading cause of disability associated with considerable societal and socioeconomic burden.¹ In 2021, the global point prevalence of activity-limiting LBP was 9.4%, meaning that over 740 million people were affected at any one time.¹ In 2018, the Lancet Low Back Pain Series Working Group identified that provision of low value care for LBP was common.²⁻⁴ Several international clinical guidelines published since 2016 have recommended prioritizing non-pharmacological treatment options for patients with LBP.⁵⁻¹⁰ Regardless, primary care management of LBP often focuses on prescription medications (e.g., non-steroidal anti-inflammatory drugs, skeletal muscle relaxants, opioids), radiological/advanced imaging techniques, and invasive therapies (e.g., interventional procedures, surgery).³

efficaces que la physiothérapie pour traiter la lombalgie, mais n'avait pas permis d'établir leur efficacité comparativement à la thérapie par l'exercice ou aux soins médicaux. Cette revue présentait toutefois plusieurs limites méthodologiques. Nous réaliserons une revue systématique actualisée afin de remédier à ces limites et de déterminer l'efficacité des soins chiropratiques comparativement à d'autres approches de soins usuelles chez les adultes atteints de lombalgie non spécifique. Nous rechercherons les essais admissibles répertoriés dans MEDLINE, AMED, Embase, CINAHL, l'Index to Chiropractic Literature et la Cochrane Library entre le 1^{er} janvier 2016 et le 31 août 2026. Des binômes d'évaluateurs indépendants procéderont à la sélection des études, à l'extraction des données et à l'évaluation du risque de biais. Nous effectuerons des méta-analyses au moyen de modèles à effets aléatoires et évaluerons, selon la méthode GRADE, le degré de certitude des données probantes pour tous les critères de jugement. Nos résultats seront diffusés dans une publication évaluée par les pairs et lors de présentations à des congrès.

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MOTS CLÉS: soins chiropratiques, lombalgie, revue systématique, efficacité

Chiropractors deliver many of the non-pharmacological treatments recommended by current guidelines⁵⁻¹², including the 2023 World Health Organization guideline for primary low back pain¹⁰. These treatments include spinal manipulative therapy, patient education, and exercise. However, the effectiveness of overall chiropractic care (i.e., combined chiropractic interventions) for LBP remains uncertain.¹³⁻¹⁸ The most recent systematic review of pragmatic studies¹³ found similar effects of chiropractic care compared to physiotherapy for LBP; however, the comparative analyses were limited to only one or two studies per outcome.¹³ The review was also unable to establish the effectiveness of chiropractic care compared to exercise therapy or medical care because of limited available evidence.¹³ Moreover, the review's findings were based on six trials of variable quality and several new trials compar-

ing chiropractic care to usual care interventions, such as medical care or physiotherapy, have since been published (e.g., Gedin *et al.*¹⁸, Goertz *et al.*¹⁹, Vining *et al.*²⁰). Further, the previous review¹³ pooled study results using standardized mean differences that are difficult to interpret,²¹ used an aggregate score for risk-of-bias assessment that may be misleading,^{22,23} and explored sources of heterogeneity and assessed the certainty of evidence using methods that were suboptimal¹³. Our objective is to conduct a systematic review that addresses these limitations to determine the effectiveness of chiropractic care compared to other usual care approaches for the management of LBP. We plan to update the economic evaluation component of the previous review¹³ in a separate study.

Methods

Standardized reporting and protocol registration

We reported our protocol in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) checklist²⁴ and registered our protocol with the Open Science Framework (<https://osf.io/gd7wz>)²⁵.

Information sources and searches

An experienced medical librarian (RJC) will search MEDLINE (Ovid), AMED (Ovid), Embase (Ovid), CINAHL (EBSCO), Index to Chiropractic Literature (chiroindex.org), and the Cochrane Library (Wiley). We will run our searches from January 1, 2016 – i.e., six months prior to the last search date of the previous systematic review¹³ – through August 31, 2026. Our database-specific search strategies will be developed and reviewed by a second librarian using the Peer Review of Electronic Search Strategies (PRESS) checklist.²⁶ Also, we will search clinical trial registries (e.g., ClinicalTrials.gov, International Clinical Trials Registry Platform) to identify ongoing trials and contact authors for publication/data availability, explore the reference lists of eligible articles and related systematic reviews (including the prior review¹³), and contact content experts to identify additional eligible studies.

Eligibility criteria

Our eligibility criteria are summarized below using the PICOS (i.e., Population, Intervention, Comparison intervention, Outcome measures, Study designs) framework.²⁷

Participants/population

Inclusion criteria

We will include studies that enrolled adults (18 years or older) with non-specific LBP (i.e., pain located between the costal margin and inferior gluteal folds, not associated with a specific pathology or condition) of any duration, with or without leg pain.

Exclusion criteria

We will exclude studies that enrolled patients with specific pathologies accounting for their LBP, such as infection, neoplasm, metastasis, osteoporosis, fracture, or inflammatory arthritis.

Intervention

In line with the prior review,¹³ our intervention of interest will be receipt of chiropractic care²⁸. This is defined as care provided by a chiropractor, including, but not limited to spinal manipulation, soft-tissue therapy, education, reassurance, and self-care advice (e.g., icing, stretching, and strengthening exercises).²⁸

Comparator/control

The comparison will be non-receipt of chiropractic care (e.g., usual medical care, physiotherapy, exercise therapist care, wait-list control [with ongoing usual care]).

Outcomes

We will extract data on all patient-important outcomes that are reported, as guided by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommendations,²⁹ including the following: (1) pain intensity, (2) physical functioning, (3) emotional functioning, (4) role functioning, (5) social functioning, (6) sleep quality, (7) patient satisfaction, (8) opioid use, and (9) adverse events^{30,31}. We will consider outcomes for physical functioning, emotional functioning, role functioning, social functioning, and sleep quality that are reported over a minimum four-week follow-up period (from baseline).

Study designs

Inclusion

We will include English- or French-language pragmatic randomized controlled trials that compared chiropractic

care to usual care for LBP delivered by other health care providers.

Exclusion

We will exclude studies that investigated chiropractic care combined with other forms of care in which the effects of chiropractic care cannot be isolated (e.g., chiropractic care plus physiotherapy vs. medical care), and studies that assessed the effect of spinal manipulative therapy as a stand-alone intervention (i.e., fastidious trials). We will contact study authors when necessary for clarification regarding eligibility and to confirm that comparison interventions were considered as usual care. We will also exclude non-randomized (quasi-experimental) controlled trials, protocols, observational studies, books and book chapters, dissertations, and other gray literature (e.g., abstracts, conference proceedings, presentations).

Study selection

Prior to initiating the screening process, and after duplicate records have been removed (see Figure 1), pairs of reviewers will conduct training and calibration exercises using standardized screening forms. After calibration, reviewers will screen, independently and in duplicate, the titles and abstracts of all identified citations and the retrieved full-text of all citations judged as potentially eligible by at least one reviewer using online systematic review software (DistillerSR, Evidence Partners, Ottawa, Canada; <https://www.distillersr.com/>). Reviewers will discuss and resolve disagreements with the help of a third, senior reviewer when required. Figure 1 includes a PRISMA flow diagram of our study selection process.

Data abstraction

We will conduct calibration exercises with a standardized data extraction form to improve inter-reviewer reliability. Next, pairs of reviewers will extract the following data independently and in duplicate from all included studies:

- (1) study characteristics (i.e., first author's last name, trial design, trial registration, study status [e.g., completed, ongoing], year of publication, country where the study was conducted, number of sites, funding source, length of follow-up),
- (2) population details (i.e., mean age, proportion of patients ≥ 65 years, proportion of patients with

male sex, proportion with LBP $\geq$ three months, population type [e.g., general population, military service members]),

- (3) chiropractic care and control group information (i.e., number of patients randomized to chiropractic or usual care; type of usual care provided, such as medical care, physiotherapy, exercise therapist care, wait-list control; number of patients analyzed per treatment arm at follow-up; reason[s] for loss to follow-up in each treatment arm), and
- (4) all patient-important outcomes including pain intensity; physical, emotional, role and social functioning; sleep quality; patient satisfaction; opioid use; and adverse events (see Table 1).

If multiple instruments were used in a study to measure the same outcome domain, we will collect data from the most commonly reported instrument among eligible trials. When trials report the same outcome at multiple timepoints, we will use data from the longest follow-up in our analyses unless there is $\geq 20\%$ missing data, in which case we will use the next longest follow-up that has $< 20\%$ missing data. We will also only include data from studies with the largest sample size in instances where two or more articles' study populations overlap by $\geq 50\%$. Disagreements will be resolved through discussion and involvement of a third senior reviewer if consensus is not achieved.

Risk of bias assessment

Pairs of reviewers will independently assess the risk of bias among eligible studies using the Risk of Bias instrument for Use in SysTematic reviews-for Randomized Controlled Trials (ROBUST-RCT),³² according to the following six core domains: random sequence generation, allocation concealment, blinding of participants, blinding of health care providers, blinding of outcome assessors, and infrequent missing outcome data for each treatment arm. For this last item, we will consider $< 10\%$ missing data as definitely low risk of bias, 10% to $< 15\%$ missing data as probably low risk of bias, 15% to $< 20\%$ missing data as probably high risk of bias^a, and $\geq 20\%$ missing

^a Reviewers will have the option of rating as 'probably low' risk of bias if the reason for missing data is unlikely to be related to the outcome, with no imbalance in numbers or reasons for missing data between intervention and control groups.

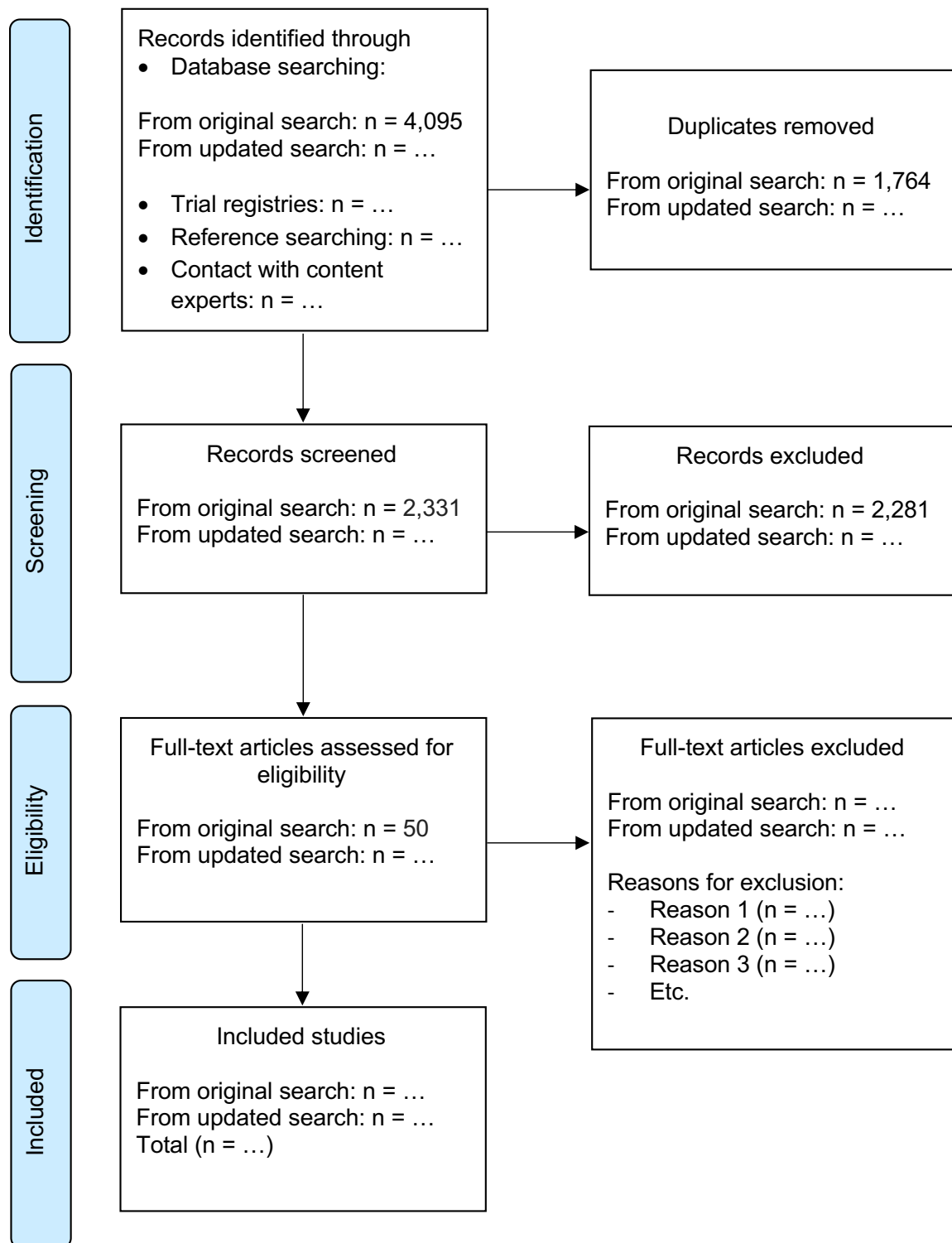


Figure 1.
PRISMA flow diagram.

Table 1.

GRADE evidence profile of chiropractic care vs. usual care in adult patients with non-specific low back pain

Study characteristics	Quality assessment					Summary of findings	Overall certainty in the evidence
No. of trials (patients)	Risk of bias	Inconsistency _a	Indirectness _b	Imprecision _c	Publication bias	Treatment association (95% CI)	
Pain intensity (e.g., 10 cm VAS for pain)							
X (...)	X	X	X	X	X	X	X
Physical functioning (e.g., 0-100 points SF-36 physical functioning scale)							
X (...)	X	X	X	X	X	X	X
Emotional functioning (e.g., 0-100 points SF-36 mental component summary scale)							
X (...)	X	X	X	X	X	X	X
Role functioning (e.g., 0-100 points SF-36 physical role functioning scale)							
X (...)	X	X	X	X	X	X	X
Social functioning (e.g., 0-100 points SF-36 social functioning scale)							
X (...)	X	X	X	X	X	X	X
Sleep disturbance (e.g., 10 cm VAS for sleep quality)							
X (...)	X	X	X	X	X	X	X
Patient satisfaction (e.g., 0-10 points satisfaction scale)							
X (...)	X	X	X	X	X	X	X
Prescription opioid receipt (yes vs. no)							
X (...)	X	X	X	X	X	X	X
Adverse events (yes vs. no) ^d							
X (...)	X	X	X	X	X	X	X

CI = confidence interval; *GRADE* = Grading of Recommendations Assessment, Development, and Evaluation; *SF-36* = short form 36 health survey questionnaire; VAS = visual analogue scale.

^a Inconsistency refers to unexplained heterogeneity of results. An I^2 of 75%-100% indicates that heterogeneity may be considerable.

^b Indirectness results if the patients, intervention, comparison/control, or outcomes of interest are different from the research question under investigation.

^c In this review, serious imprecision refers to situations in which the 95% CI includes both benefit and harm.

^d Examples of manual therapy and/or patient-important analgesic-induced adverse events include the following: muscle soreness, joint pain, stiffness, headache, dizziness, nausea, vomiting, constipation, radiating symptoms, paresthesia, or fatigue.^{30,31}

data as definitely high risk of bias. For all but the last item, response options will be categorized as ‘definitely or probably yes’ and ‘definitely or probably no.’ Reviewers will then judge the risk of bias related to each of the six items as ‘definitely or probably low’ (assigned as low risk of bias) and ‘definitely or probably high’ (assigned as high risk of bias).³² Disagreements between reviewers will be resolved as previously described.

Synthesis and presentation of findings

For treatment effects that are reported as binary outcomes (e.g., opioid use, adverse events), we will calculate the odds ratio (OR) and its corresponding 95% confidence interval (CI). We will then transform the OR to a relative risk (RR) using the formula: $RR = OR / (1 - \text{baseline risk} * (1 - OR))$ and then calculate the risk difference (RD) using the formula: $RD = \text{baseline risk} * (RR - 1)$.³³ The

baseline risk (i.e., proportion of patients in the non-chiropractic care control group who had the events) for each outcome will be calculated as the median control group risk across included trials.

With continuous outcomes, pooling effect estimates from different instruments that report on a common domain is often done by converting each instrument to standard deviation (SD) units and combining effects across studies as the standardized mean difference (SMD). This approach has important limitations including difficulties in interpretation and vulnerability to baseline heterogeneity of trial participants.^{21,34} Therefore, we will use linear transformation – assuming instruments reporting on shared domains have similar measurement properties – to convert all measures on a common domain to the most frequently reported scale among eligible trials.^{34–36} For example, we will convert all instruments measuring pain intensity to a 10-cm visual analogue scale (VAS), higher scores are worse; physical functioning to the 100-point 36-item Short Form Survey (SF-36) physical functioning scale, higher scores are better; emotional functioning to the 100-point SF-36 mental component summary scale, higher scores are better; role functioning to the 100-point SF-36 scale of role limitations due to physical problems, higher scores are better; social functioning to the 100-point SF-36 social functioning scale, higher scores are better; sleep disturbance to a 10-cm VAS, higher scores are worse; and patient satisfaction to a 10-point satisfaction scale, higher scores are better.³⁵

After converting all continuous outcome measures in common domains to a single tool, we will pool treatment effects as the weighted mean difference (WMD) and associated 95% CI and co-present the corresponding minimally important difference (MID) (i.e., the smallest amount of improvement in a treatment outcome that patients recognize as important).^{34,36} We will use anchor-based MIDs of 1.5 cm on the 10-cm VAS for pain intensity,³⁷ 10 points on the 100-point SF-36 subscales for physical, emotional, role, and social functioning,³⁸ 1 cm on the 10-cm VAS for sleep quality,³⁹ and 1 point on the 10-point scale for patient satisfaction⁴⁰. We will then calculate the probability of achieving greater than or equal to the MID with chiropractic care and with the control intervention.^{21,34} We will use the mean and SD of the control and chiropractic care group responses from each included trial, with the established MID for the outcome in question to estimate the

probability of achieving greater than or equal to the MID in the control and chiropractic care groups, respectively. We will then use the probabilities from both groups to acquire the RD for achieving greater than or equal to the MID with chiropractic care in each trial. The estimated RDs will then be pooled across trials using the inverse variance method.^{21,34}

Modelling assumptions for estimating the RD of achieving the MID assume that SDs of outcome measurements are the same in both the treatment and control groups, and that change scores in both groups are normally distributed. To verify modelling assumptions, we will compare SDs between treatment and control groups, and calculate the mean effect score $\pm$ 2 SDs in each treatment group for all trials that contribute to our analyses to identify any cases in which the distributions are substantially skewed.^{34,41}

Heterogeneity will be examined by visual inspection of forest plots (e.g., similarity of point estimates, extent of overlap of CIs), and assessment using the I^2 statistic. We will use the DerSimonian–Laird method and random-effects models for the meta-analysis of all outcomes reported in two studies or more. Random-effects models are more conservative in that they consider both within- and between-study variability.^{41,42} We will summarize results descriptively when meta-analysis is not possible (e.g., one study per outcome). For all outcomes reported in 10 studies or more, we will investigate small-study effects using contour-enhanced funnel plots and will perform Egger’s test for continuous outcomes and Harbord’s test for binary outcomes.^{43,44} All data analyses will be performed in Stata (StataCorp, Release 18.0, College Station, TX, USA), and comparisons will be 2-tailed using a statistical significance threshold (α) of 5%.

Subgroup analyses

We will explore sources of heterogeneity in our pooled analyses according to the following subgroups:

- (1) different comparators (e.g., usual medical care, physiotherapy, exercise therapist care, wait-list control),
- (2) different study populations (e.g., general community, military service members),
- (3) patient age (e.g., < 65 years vs. $\geq$ 65 years),
- (4) duration of LBP at baseline (acute vs. chronic),

- (5) trials with shorter (< 3 months) vs. longer ($\geq$ 3 months) follow-up, and
- (6) risk of bias (on an item-by-item basis).

We hypothesize that trials of younger patients, patients with acute pain, of shorter follow-up, and at higher risk of bias will show larger beneficial effects with chiropractic care.¹³⁻¹⁵

We will conduct subgroup analyses when at least two studies are available in each subgroup and we will perform test of interaction ($p < 0.05$) for subgroup effects.⁴⁵ We will assess the credibility of significant subgroup effects using the Instrument for Assessing the Credibility of Effect Modification Analyses (ICEMAN) criteria.⁴⁶

Certainty in the evidence

We will assess certainty of the evidence for all outcomes using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach.^{47,48} This approach considers risk of bias, inconsistency, indirectness, imprecision, and publication bias. We will use the 'Making GRADE the Irresistible Choice' (MAGIC) platform (<https://app.magicapp.org>) to develop summary of finding tables and rate the overall certainty of evidence as high, moderate, low, or very low depending on the grading of the individual domains (Tables 1 and 2).^{47,48} We will not rate down certainty in the evidence for risk of bias if the subgroup analysis shows no association of treatment effects between trials at low and high risk of bias (on a component-by-component basis).⁴⁹ If a significant subgroup effect is found, we will present the pooled effect

for studies at low risk of bias (for affected domains) and not rate down the certainty of evidence for risk of bias. If we cannot conduct subgroup analysis (e.g., all trials are at risk of bias), then we will report the pooled effect estimate but rate down our certainty of evidence for risk of bias.

Ethics

We do not require research ethics approval to conduct this systematic review as we will not be requiring access to, or use of, individual patient data.

Discussion

Low back pain is the leading cause of years lived with disability worldwide.¹ In Canada, annual direct health care costs associated with LBP have been estimated at between \$6 and \$12 billion.⁵⁰ Spinal manipulative therapy, often provided by chiropractors as part of a multimodal care approach,²⁸ has been shown in some reviews^{14,15,17} (but not all¹⁶) to be effective for both acute and chronic LBP in terms of pain reduction and improvement in functional status. However, several of these reviews¹⁴⁻¹⁶ included studies that investigated spinal manipulative therapy delivered by non-chiropractic practitioners or as a stand-alone intervention. Findings from prior reviews^{13,17,51,52} also suggest that the clinical and cost effectiveness of overall chiropractic care (i.e., combined chiropractic interventions) for LBP remain uncertain. Moreover, several new trials have been published.^{18-20,53} Our systematic review will aim to identify studies addressing the clinical effectiveness of chiropractic care compared to usual care approaches offered by other provider groups (e.g.,

Table 2.
Quality of evidence levels for GRADE^{47,48}

Quality level	Definition
High	We are very confident that the true effect lies close to that of the estimate of the effect
Moderate	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

GRADE = Grading of Recommendations Assessment, Development, and Evaluation.

medical care, physiotherapy) among adult patients with non-specific LBP. The results of our study may inform policy-makers, health care practitioners, and patients on whether to incorporate chiropractic care when managing non-specific LBP. We plan to conduct a systematic review of economic evaluations of chiropractic care for LBP in a future study.

Strengths and limitations

Strengths of our review will include a comprehensive search for eligible randomized controlled trials, appraisal of the risk of bias among individual studies, and use of the GRADE approach to rate the certainty of evidence. We will convert all significant pooled mean effects to RDs to facilitate interpretation, and evaluate the assumptions underlying our outcome transformation and MID-based RD estimates. We will also use pre-defined subgroup analyses to explore sources of heterogeneity and assess the credibility of all potential subgroup effects. A limitation of our review is that MID-based estimates can underestimate treatment effects if most patients (e.g., > 95%) in both groups experience effects greater than the MID.³⁴ Another limitation is we will exclude non-English and -French publications, which may lead to selection bias.

Knowledge translation

We will publish our work in a peer-reviewed journal, and present our results at relevant conferences, to disseminate our findings.

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