

BMJ Open Effectiveness and safety of moxibustion treatment for non-specific lower back pain: protocol for a systematic review

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ABSTRACT

Introduction Many patients experience acute lower back pain that becomes chronic pain. The proportion of patients using complementary and alternative medicine to treat lower back is increasing. Even though several moxibustion clinical trials for lower back pain have been conducted, the effectiveness and safety of moxibustion intervention is controversial. The purpose of this study protocol for a systematic review is to evaluate the effectiveness and safety of moxibustion treatment for non-specific lower back pain patients.

Methods and analysis We will conduct an electronic search of several databases from their inception to May 2017, including Embase, PubMed, Cochrane Central Register of Controlled Trial, Allied and Complementary Medicine Database, Wanfang Database, Chongqing VIP Chinese Science and Technology Periodical Database, China National Knowledge Infrastructure Database, Korean Medical Database, Korean Studies Information Service System, National Discovery for Science Leaders, Oriental Medicine Advanced Searching Integrated System, the Korea Institute of Science and Technology, and KoreaMed. Randomised controlled trials investigating any type of moxibustion treatment will be included. The primary outcome will be pain intensity and functional status/disability due to lower back pain. The secondary outcome will be a global measurement of recovery or improvement, work-related outcomes, radiographic improvement of structure, quality of life, and adverse events (presence or absence). Risk ratio or mean differences with a 95% confidence interval will be used to show the effect of moxibustion therapy when it is possible to conduct a meta-analysis.

Ethics and dissemination This review will be published in a peer-reviewed journal and will be presented at an international academic conference for dissemination. Our results will provide current evidence of the effectiveness and safety of moxibustion treatment in non-specific lower back pain patients, and thus will be beneficial to patients, practitioners, and policymakers.

Trial registration number CRD42016047468 in PROSPERO 2016

INTRODUCTION

More than 70% of people suffer from lower back pain in developed countries.¹

Strengths and limitations of the present study protocol

- Our review provides a systematic, objective, and comprehensive evaluation of the effectiveness and safety of moxibustion treatment in patients with lower back pain that is non-specific.
- Our review and meta-analysis provide new and useful information for practitioners, policymakers, and patients.
- Various treatments with moxibustion and clinical outcomes reviewed in our study will help to design clinical trial studies of moxibustion treatment for non-specific lower back pain.
- Chinese and Korean databases will be searched to avoid a language bias.
- The major limitation of our study protocol is that some of the reviewed trials may have small sample sizes; this limitation affects our objective and comprehensive assessment of the risks and benefits of moxibustion treatment for non-specific lower back pain.

Approximately 90% of back pain is non-specific,² indicating that in most people the pathophysiological origin of the back pain cannot be specified.¹ Moreover, specifying and treating the factor that contributes to lower back pain is difficult because several co-related factors are involved, including psychological, work-related, and other individual factors.³ Back pain is spontaneously relieved, but 5–20% of acute back pain patients suffer from chronic or persistent lower back pain.^{4–7} The widely accepted definition of chronic lower back pain is a pain that persists for >3 months.⁸ Even though conventional treatments such as medication or surgery have shown some efficacy against lower back pain,^{9 10} many lower back pain patients are dissatisfied with conventional treatment.¹¹

The proportion of patients using complementary and alternative medicine to



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treat lower back is increasing.¹² Acupuncture plays an important role in Traditional East Asian Medicine (TEAM) treatment of pain.¹³ Several systematic reviews on the effectiveness and safety of acupuncture treatment in lower back pain patients have been published.^{14–17} Moxibustion is an important treatment modality in TEAM treatment that stimulates acupoints with the heat energy of a burning herbal preparation.^{13 18} Absorption of the therapeutically active components of the herbal preparation also contributes to the effect of moxibustion.¹⁸ In TEAM theory, moxibustion treatment promotes qi stimulation and resolves qi stagnation at an acupoint.¹⁸ Two types of moxibustion, direct moxibustion and indirect moxibustion, are widely used in TEAM treatment. Systematic reviews have been published about the effectiveness of moxibustion in several diseases, including insomnia, hypertension, irritable bowel syndrome, and constipation.^{19–22} However, a systematic review that focuses especially on the effectiveness of moxibustion treatment in non-specific lower back pain has not been published yet.

A systematic review summarises the evidence of relevant current clinical trial studies; this effort provides supportive information for the design of future clinical trial studies. A systematic review of studies on the effectiveness of Traditional Chinese Medicine (TCM) treatment of back pain was published in 2015.¹ This review of TCM treatment for lower back pain deals with studies involving whole TCM interventions such as acupuncture, acupressure, moxibustion, cupping, Gua Sha, qigong, herbal medicine, and tuina treatments. However, the focus of that review was only pain intensity and disability measured with continuous outcome variables such as the visual analogue scale. There were no articles on moxibustion treatment for lower back pain included in the review; however, other parameters such as quality of life, work related outcome, side effects, and the proportion of responders are also important and valuable clinical outcome variables in patients with lower back pain. If we do not restrict outcome measures to only the intensity of pain and disability measured by continuous outcome variables, we can identify more moxibustion clinical trials, and include Korean databases because moxibustion therapy is widely used in Korea for the treatment of lower back pain. The last search by the previous review was conducted in 2014; however, additional clinical trials have been conducted since. Thus, we could include and analyse more moxibustion clinical trials than the previous review. Also, the range of interventions explored in that previous review is too broad to clarify the critical factors related to moxibustion treatment of lower back pain that are of interest to practitioners and researchers; such factors include the treatment duration, position, intensity, frequency, species of moxa, various outcome parameters, and side effects of moxibustion treatment. A systematic review of studies on the effectiveness of heat sensitive moxibustion treatment for a lumbar disc herniation has also been published.²³ However, as the prevalence of lower back pain that is

secondary to a lumbar disc herniation (LDH) is low, it is not our target condition. Only 3–4% of patients with lower back pain who came to a primary clinic suffered from spinal stenosis or a lumbar disc herniation.²⁴ L5 and S1 spinal nerve root damage due to disc protrusion or degenerative changes in the vertebrae are common causes of lower back pain in patients with a lumbar disc herniation.²⁵ Hence, non-specific lower back pain and LDH have different pathophysiologies.

Our preliminary search on moxibustion treatment for lower back pain found several clinical studies with various experimental designs; for example, moxibustion versus usual care or conventional treatment, moxibustion versus another TCM intervention such as (electro) acupuncture, and moxibustion adjuvant therapy with acupuncture, among others. Thus, we believe that our study will overcome the limitations of previous systematic reviews of studies involving lower back pain and TCM.^{1 23}

To our knowledge, a systematic review that focuses on the effectiveness of various types of moxibustion treatment for non-specific lower back pain and includes Chinese and Korean studies has not been published. Thus, we propose to conduct a systematic review that focuses on the effectiveness and safety of moxibustion treatment in patients with non-specific lower back pain. We will summarise the current evidence and provide useful information to practitioners, patients, and policymakers. A summary of the current evidence from moxibustion clinical trial studies of lower back pain will benefit the development of future moxibustion clinical trial protocols. In the present article, we describe our methods and plan for a systematic review.

Objectives

The objective of the present review is to evaluate systematically the effectiveness and safety of moxibustion treatment compared with placebo control, conventional treatment, or no treatment in non-specific lower back pain patients evaluated by pain intensity and functional status/disability.

METHODS

Study registration

The systematic review protocol registration number in the International Prospective Register of Systematic Reviews (PROSPERO) is CRD42016047468. This systematic review protocol complies with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) statement guidelines.^{26 27} In addition, our review will be conducted in compliance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement guidelines.²⁸

Criteria for study inclusion

Type of studies

We will include only randomised controlled trials (RCTs) in this review. Several Chinese trials do not provide detailed description of the randomization method used. We will include such studies if the authors have mentioned

the randomization method used (随机). However, we will grade these studies as high in the 'risk of bias assessment' if detailed description on the randomization process is not provided. Furthermore, if an incorrect randomization method such as coin toss was used, the study will not be included.

Type of participants

Patients diagnosed with only non-specific lower back pain will be included in the review. Trials studies of lower back pain due to other pathologies such as lumbar disc herniation, fibromyalgia, tumour, compression fracture, infection, trauma, cauda equina syndrome, vertebral canal stenosis, scoliosis, or ankylosing spondylitis will be excluded. There will be no restriction on sex, age, ethnicity, disease duration or disease severity.

Type of interventions

Moxibustion therapy will be compared with a placebo control, conventional treatment, no treatment, and an unproven control treatment. Moxibustion adjunctive therapy in combination with conventional treatment will be compared with conventional treatment alone. Any type of moxibustion will be included, regardless of the treatment frequency, duration, material, type, and method. Studies involving direct moxibustion, indirect moxibustion, warm needling, moxa-burner moxibustion, heat sensitive moxibustion, natural moxibustion, herbal patching, and crude drug moxibustion will also be included. Research that compares different moxibustion materials, doses, or durations of moxibustion treatment will not be included. Studies that evaluated the effect of moxibustion with at least 1 day of follow-up will be included.

Primary outcomes

Pain intensity and functional status/disability will be a primary outcome.

Chief complaints of non-specific low back pain are pain and functional disability. Moreover, there are no objective biomarkers and parameters to evaluate lower back pain. Therefore, we selected pain intensity and functional status/disability as primary outcomes. These primary outcomes were also widely used in several of the previous systematic reviews on various interventions for lower back pain.^{1 29-33} Other important outcomes used in these reviews were considered secondary outcomes of our review. Pain intensity will be evaluated using the visual analogue scale (VAS)³⁴ or the numerical rating scale (NRS).³⁵ As VAS is continuous data and NRS is dichotomous data, VAS and NRS will not be mixed in the meta-analysis. Functional status/disability will be evaluated using validated measurement tools such as the Roland Morris Disability Questionnaire (RMDQ) or the Oswestry Disability Scale.^{36 37}

Secondary outcomes

The secondary outcomes will include the following: (1) global measurements of recovery or improvement,

such as subjective symptom improvement, the proportion of responders, overall improvement, and perceived recovery; (2) work-related outcomes, such as productivity, return to work status, and the number of days absent from work; (3) radiographic improvement of structure; (4) quality of life measurements using validated tools such as the Short Form Survey Instrument (SF-36)³⁸ and Euroqol-5D (EQ-5D)³⁹; and (5) complications and adverse events.

Search methods

Electronic search

We will conduct an electronic search of several databases from their inception to May 2017. Four English databases will be searched, namely, Embase (Ovid), Medline (PubMed), the Cochrane Central Register of Controlled Trials (CENTRAL), and the Allied and Complementary Medicine Database (AMED); three Chinese database will be searched, namely, the Wanfang Database, the Chongqing VIP Chinese Science and Technology Periodical Database (VIP), and China National Knowledge Infrastructure Database (CNKI); and six Korean databases will be searched, namely, the Korean Medical Database (KMBASE), the Korean Studies Information Service System (KISS), National Discovery for Science Leaders (NDSL), the Oriental Medicine Advanced Searching Integrated System (OASIS), Korea Institute of Science and Technology (KISTI), and KoreaMed. The search term will be composed of two parts, moxibustion (eg, moxibustion or moxabustion or moxa or artemisia or mugwort) and back pain (eg, lower back pain, sciatica, radiculopathy, lumbago, backache, back pain, or lumbosacral). The online Supplementary Appendix 1 presents our detailed search strategy that will be specific to Medline (PubMed).

Searching other resources

PROSPERO, the International Clinical Trials Registry Platform (ICTRP), and ClinicalTrials.gov will also be searched to identify systematic reviews or ongoing/completed clinical trials. We will conduct a hand search of relevant journals and their conference proceeding. Theses and bibliographic references of included trials will also be reviewed.

Analysis

Study selection

Two review authors (J Leem and Y Cho) will independently screen titles and abstracts in retrieved article lists from independent electronic and hand searches to exclude any obviously irrelevant articles. The full text of the remaining articles will be downloaded to assess their eligibility for inclusion in our review according to predefined criteria. Disagreement between these two authors will be resolved by discussion. If these authors do not reach an agreement, a third review author (D Nam) will make the final decision.

Data extraction and management

Two review authors (J Leem and Y Cho) will read all included articles and extract data according to a predefined data sheet that includes the publication year, author, title, journal, country, hospital setting, study design, allocation concealment, randomization method, blinding, participants number, dropout number, intervention of treatment and control groups, treatment frequency and number, diagnostic criteria, disease duration, disease severity, outcome and results, and adverse event. Disagreement between these two authors will be resolved by discussion. If these authors do not reach an agreement, a third review author (D Nam) will make the final decision. We will request via email that the corresponding author of the original study send data when the results are ambiguous.

Assessment of reporting quality and risk of bias

Two review authors (J Leem and Y Cho) will independently assess the risk of bias according to the Cochrane risk of bias tool⁴⁰ outlined in the Cochrane Handbook for Systematic Reviews for Intervention.⁴¹ Risk of bias assessment categories will include the following: (1) allocation concealment; (2) random sequence generation; (3) blinding of outcome assessors; (4) blinding of participants; (5) incomplete outcome data; (6) selective outcome reporting; and (7) other biases. The level of the risk of bias will be evaluated as either a low, high, or unclear risk of bias. Disagreement between these two authors will be resolved by discussion. If these authors do not reach an agreement, a third review author (D Nam) will make the final decision.

Unit of analysis

If studies measure the same outcome repeatedly, we will perform an analysis according to a timeline definition. Immediate follow-up will mean up to 1 week after the last intervention. Short-term follow-up will mean from 1 week to 3 months. Intermediate-term follow-up will mean from 3 months to 1 year after the last treatment. Long-term follow-up will mean more than 1 year after the last treatment. If two or more moxibustion treatment arms exist, the number of control group patients will be divided by the number of moxibustion treatment groups and will be synthesised in a meta-analysis

Measures of a treatment effect

For dichotomous data, a risk ratio (RR) and the 95% confidence interval (CI) will be used to estimate a treatment effect. For continuous data, the mean difference (MD) and 95% CI will be used to estimate a treatment effect when the same outcome scale or method is used. Standardised mean difference (SMD) and 95% CI will be used to estimate a treatment effect when a different outcome scale or method is used.

Managing missing data

We will contact the corresponding author of an article via email to obtain any missing data. If there is no response to

an email, we will exclude the data from our analysis, and describe the reason and impact of this exclusion in the Discussion section.

Assessment of a reporting bias

Publication bias will be assessed visually using funnel plot asymmetry if more than 10 articles are included.⁴¹ An Egger's regression test will be used to quantitatively evaluate funnel plot asymmetry.⁴²

Assessment of heterogeneity

The heterogeneity of included studies will be quantitatively evaluated using an I^2 statistic that is derived from a χ^2 test. The I^2 statistic will be interpreted according to the following criteria: (1) 75–100% will indicate considerable heterogeneity; (2) 50–90% will indicate substantial heterogeneity; (3) 30–60% will indicate moderate heterogeneity; (4) 0–40% will indicate little to no heterogeneity. In this manner, an I^2 statistic of >50% will indicate the presence of substantial heterogeneity for the included studies.⁴³ If the I^2 statistic is >75%, a meta-analysis will not be conducted.⁴⁴ Instead, we will qualitatively describe the effectiveness and safety of moxibustion treatment. If the I^2 statistic belongs to both heterogeneity categories, we will use both adjectives. For example, if the I^2 statistic is 55%, we will express the heterogeneity as 'moderate to substantial heterogeneity.'

Data synthesis and grading of quality of evidence

The Review Manager (REVMAN) software for Windows will be used to perform a meta-analysis and to calculate the risk ratio or (standardised) mean difference (Version 5.3; Copenhagen; The Nordic Cochrane Center, The Cochrane Collaboration, 2014). We will adopt a random effect model when the I^2 statistic is >50%, otherwise we will adopt a fixed effect model in a meta-analysis. If we are unable to conduct meta-analysis due to lack of clinical studies or heterogeneity, we will present the effect size and 95% CI of every outcome in each clinical trial and describe the meaning of important results in the discussion section qualitatively. To summarise the findings of the meta-analysis and describe the strength of evidence, we will use the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) approach.⁴¹

Subgroup analysis

To identify heterogeneity between the included studies, a subgroup analysis will be conducted if there is a sufficient number of articles in each subgroup. The criteria of a subgroup analysis will be as follows: (1) disease duration, such as chronic (>3 months) or acute lower back pain (we will conduct a subgroup analysis according to disease duration even though there are not sufficient number of included studies); (2) type of control group, such as placebo moxibustion, conventional treatment, other TCM treatment, and no treatment; (3) type of moxibustion, such as direct moxibustion, indirect moxibustion, warm needling moxibustion, moxa burner moxibustion, heat sensitive moxibustion, and crude drug moxibustion;

(4) species of herb used in the moxibustion treatment; and (5) treatment number, frequency, and duration.

Sensitivity analysis

If there are a sufficient number of included articles, a sensitivity analysis will be carried out after removing low quality articles to identify the robustness of a result. The methodological quality will be assessed according to the 'risk of bias' tool.⁴⁰ After excluding low quality articles that have more than three 'risk of bias categories' graded as 'high risk of bias,' we will conduct a second meta-analysis. The results and effect size of the two meta-analyses will be compared and discussed.

DISCUSSION

The purpose of this proposed systematic review and meta-analysis will be to evaluate the effectiveness and safety of moxibustion treatment of non-specific lower back pain. When compared with acupuncture research, the quantity and quality of moxibustion therapy research is relatively low. The STandards for Reporting Interventions in Clinical Trials of Moxibustion (STRICTOM) was published in Chinese in 2013,⁴⁵ but has not been widely adopted and translated into English. A recent systematic review was published on TCM treatment of lower back pain.¹ This review included a variety of interventions that are practised in TCM, such as acupuncture, moxibustion, herbal medicine, cupping, and manual therapy, among others. However, the various interventions that were included in that review have too broad of a range to appropriately evaluate the issues that are specific to moxibustion treatment of lower back pain. Moreover, it did not include any trial studies of moxibustion treatment. A systematic review has also been published regarding the effectiveness of heat sensitive moxibustion for lumbar disc herniation.²³ However, this review is not concerned with non-specific back pain, but rather, lower back pain that is secondary to lumbar disc herniation. Therefore, the protocol described here is for the first systematic review and meta-analysis on the effectiveness and safety of any type of moxibustion treatment in non-specific lower back pain patients. We anticipate that our review and meta-analysis will provide useful information to practitioners, policymakers, and patients.

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Contributors DN conceived of the study. The protocol was drafted by JL and YC. The search strategy was developed by SL and SL. The inclusion criteria were developed by YP and BS. The authors JK and E-K revised the manuscript. The authors YL, I-HH, and H-JL developed the analysis plan. JL submitted the manuscript for publication. All authors have read and approved the final manuscript.

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Competing interests None declared.

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Data sharing statement As it is protocol of systematic review, there are no data to share.

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