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Dose-response relationship between acupuncture time parameters and the effects on chronic non-specific low back pain: a systematic review and Bayesian model-based network meta-analysis protocol

Qin Luo , Chunyan Yang, Liuyang Huang, Xu Guixing , Tian Hao, Mingsheng Sun , Fan-rong Liang

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QL and CY contributed equally.

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School of Acu-Mox and Tuina, Chengdu University of Traditional Chinese Medicine, Chengdu, China

Correspondence to
Dr Fan-rong Liang;
acuresearch@126.com

ABSTRACT

Introduction Low back pain (LBP) is a major global public health problem and the majority (nearly 90%) of patients with LBP suffer from non-specific LBP (NSLBP). Acupuncture has been widely used for relieving pain and is recommended as a first-line treatment in LBP guidelines. However, the guidelines do not recommend a specific acupuncture temporal dosage. A Bayesian model-based network meta-analysis (MBNMA) will be conducted to optimise the dosages of time parameters (session, frequency and duration).

Methods and analysis The following databases will be searched from their inception until 1 July 2023: MEDLINE (via PubMed), Cochrane Central Register of Controlled Trials (CENTRAL), EMBASE, Web of Science, Cumulative Index to Nursing & Allied Health Literature (CINAHL), alternative health research database (Alt HealthWatch), China National Knowledge Infrastructure (CNKI), Wanfang Database, VIP Database for Chinese Technical Periodicals, ClinicalTrials.gov, the WHO's International Clinical Trial and Chinese Clinical Registry. RCTs assessing the effects of acupuncture on chronic NSLBP will be selected. The primary outcome measure will be the improvement in pain intensity at different acupuncture time points. The MBNMA will be performed using R V.4.2.1 with related R packages. Risk of Bias V.2.0 and Confidence in Network Meta-Analysis will be used to assess the evidence quality.

Ethics and dissemination Ethical approval is not required for literature-based studies. The results will be published in peer-reviewed journals or conferences.

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STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study will be the first dose-response Bayesian model-based network meta-analysis (NMA) on acupuncture temporal dose parameters (session, frequency and duration).
⇒ The study will adhere strictly to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) statement and PRISMA-NMA guidelines, ensuring transparency and robust methodology.
⇒ By employing the Confidence in Network Meta-Analysis framework, the study will enhance the confidence in the quality of evidence, thereby improving the overall outcome.
⇒ Heterogeneity may arise due to differences between Eastern and Western research, electroacupuncture and manual acupuncture, and the selection of acupoints.
⇒ The acupuncture effect may be underestimated due to the sham acupuncture control.

INTRODUCTION

Low back pain (LBP) is a significant global public health issue. It has been identified as one of the leading causes of disability worldwide and has ranked ninth in terms of the global burden of diseases since 2019.[1] LBP is characterised by pain, muscle tension or stiffness localised below the costal margin and above the inferior gluteal folds, with or without accompanying leg pain. Chronic LBP is defined as pain that persists for more than 12 weeks. Among individuals with LBP, approximately 90% are diagnosed with non-specific LBP (NSLBP), which lacks a clear nociceptive cause.[2] Most people experience acute LBP at least once in their lifetime, with a high percentage progressing chronic LBP.[3] Studies have shown that 67% of people with NSLBP continue to experience pain after 3 months, and 45% still have pain after 12 months.[4] NSLBP commonly originates from the back muscles, joints or ligaments. Furthermore, psychological factors are highly prevalent in adults with chronic NSLBP.[5] Due to the risks associated with

opioid use and the limited effectiveness of pharmaceutical treatments, non-pharmacological approaches such as acupuncture, exercise and physical therapy have become the first-line treatments for LBP.[3 6] Acupuncture, an ancient non-pharmacological therapy, has been widely used for pain relief and can effectively alleviate pain sensations and improve negative emotions associated with pain, being a cost-effective option for long-term care.[7–10] Acupuncture is recommended in various LBP treatment guidelines and is covered by the US Medicare proposals.[11–14]

Previous meta-studies on acupuncture for NSLBP have primarily focused on acupuncture efficacy and different acupuncture methods.[15–17] However, the acupuncture 'dose' has been overlooked, despite its potential direct impact on trial outcomes, whether positive or negative.[18] The lack of guidance regarding the session, frequency and duration of acupuncture treatment has led to significant variations in the acupuncture frequency for chronic NSLBP, ranging from once a week to once a day, with session numbers varying from 3 to 26 and durations spanning from days to months.[15] White *et al* first described the concept of an 'adequate acupuncture dose' for chronic knee pain, which includes at least six sessions once a week, with a minimum needle retention time of 20 min, and achieving the *Deqi* sensation.[19] The dose-response relationship between acupuncture sessions or durations has been evaluated in some advanced meta-analysis studies for chronic pain, chronic prostatitis/chronic pelvic pain and major depression.[20–22] Therefore, it is essential to determine the optimal acupuncture temporal dose (session, frequency and duration) that can yield the maximum therapeutic benefit (MTB) for NSLBP.

Network meta-analysis (NMA) is commonly used to synthesise evidence from multiple studies comparing various treatments simultaneously.[23] Model-based meta-analysis is a widely used approach to understand the pharmacodynamic profile of different agents, specifically the dose-response and time-course relationships.[24] In this study, the session, frequency, and duration will be considered the 'dose', and the dose-response model-based NMA (MBNMA) approach will be employed. This approach allows for the pooling of relative effects within studies, retains randomisation and enables the testing of network consistency between direct and indirect evidence while incorporating all available evidence at different time points.[25] Therefore, the objective of this MBNMA protocol is to systematically analyse the dose-response relationship of acupuncture for chronic NSLBP.

Objective

This study aims to compare the efficacy of acupuncture for chronic NSLBP using different acupuncture time doses (sessions, frequencies, and durations) and to identify the optimal acupuncture temporal dose parameters.

METHODS

This protocol will be reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) and PRISMA-NMA guidelines.[26 27]

Criteria for including studies in this review

Types of studies

Only randomised controlled trials (RCTs) will be included. There will be no restrictions based on language, region or sample size. Excluded studies will include those with a crossover design, non-RCTs, case series/reports, expert experience, animal experiments and duplicated articles.

Types of participants

Adult patients diagnosed with chronic non-specific LBP according to the North American Spine Society guidelines will be included. Inclusion criteria include being 18 and older, experiencing chronic NSLBP for more than 12 weeks, with or without leg pain, and without other pathoanatomical causes.[12]

Participants who meet any of the following criteria will be excluded from the study: being under 18 years old (adolescents), having LBP caused by specific pathoanatomical factors (eg, trauma, spine malformation, tumour and infection), experiencing radicular pain (eg, herniated disc and spinal stenosis), presenting with anxiety or depression or being pregnant.

Types of interventions

For this review, only body acupuncture, including manual and electroacupuncture, defined as needle stimulation of acupoints, will be included. Other types of acupuncture will be excluded, such as warming-needle, auricular acupuncture, scalp acupuncture, laser acupuncture, dry needling, trigger point acupuncture not based on traditional Chinese medicine theory, acupressure, intradermal needling, acupoint injection, and embedding.

Types of control groups

The included comparators will be classified as follows:

1. Placebo acupuncture: Superficial insertion or simulation stimulus with needles in the same acupoints, non-relevant acupoints or non-acupoints. Placebo needles, such as Streitberger needles that could create the sensation of being needled, will also be included.
2. Conventional therapy: Primarily non-steroidal anti-inflammatory drugs, physiotherapy, education, usual care or a combination of these.
3. Blank control or waiting control: Participants in these groups will not receive acupuncture before the end of the trial.
4. Different time doses of acupuncture control: Studies combining two or more acupuncture methods or comparing different acupoints or forms of acupuncture will be excluded.

Types of outcome measures

Studies meeting any of the following primary outcomes will be included.

Primary outcomes

Pain intensity. Changes in pain intensity at different treatment temporal nodes will be measured using the Visual Analogue Scale (VAS), Numerical Rating Scale (NRS), Brief Pain Inventory (BPI), McGill Pain Questionnaire, MOS item short from health survey(SF-36) bodily pain or other chronic pain grade scales.

Secondary outcomes

1. Pain function. Change in back-specific functional status (eg, Oswestry Disability Index, Roland Morris Disability Questionnaire).
2. Safety. The proportion of participants experiencing adverse effects associated with all intervention approaches will be considered as a measure of safety. Adverse reactions will be defined as any type of adverse event, side effect, complication or event leading to treatment discontinuation.

Search methods for identification of studies

The following databases will be searched from database inception to 1 July 2023: MEDLINE (via PubMed), Cochrane Central Register of Controlled Trials (CENTRAL), EMBASE, Web of Science (WoS), Cumulative Index to Nursing & Allied Health Literature (CINAHL), alternative health research database (Alt HealthWatch), China National Knowledge Infrastructure (CNKI), Wanfang Database and VIP Database for Chinese Technical Periodicals. Meanwhile, ClinicalTrials.gov, the WHO's International Clinical Trial and Chinese clinical registry will be searched for unpublished data. The relevant systematic reviews will be retrieved and reviewed to further locate potential trials. Incomplete or missing data will be provided by contacting the corresponding authors.

The search strategy for databases will involve a combination of subject headings and keywords using Boolean terms. For instance, the search strategy for PubMed will be as shown in box 1. The search terms used will include: 'acupuncture', 'acupuncture therapy', 'needling', 'electroacupuncture' and 'electric acupuncture' combined with terms such as 'low back pain', 'pain*, low back', 'back pain*, lower', 'backache*, low', 'dorsalgia', 'lumbago', 'lumbar pain', etc. The search will also include terms like 'random*' and 'clinical' to identify relevant studies. For databases in Chinese, the search terms will be translated accordingly to ensure comprehensive coverage.

Box 1 Search strategy for PubMed database

#1 acupuncture (MeSH terms).
#2 acupuncture therapy (MeSH terms).
#3 needling (title/abstract).
#4 electroacupuncture (title/abstract).
#5 electric acupuncture (title/abstract).
#6 #1 OR #2 OR #3 OR #4 OR #5.
#7 low Back Pain (MeSH terms).
#8 pain*, low back (title/abstract).
#9 back pain*, lower (title/abstract).
#10 low* back pain* (title/abstract).
#11 low backache* (title/abstract).
#12 ache*, low back (title/abstract).
#13 back ache*, low (title/abstract).
#14 backache*, low (title/abstract).
#15 lumbago (title/abstract).
#16 dorsalgia (title/abstract).
#17 lumbar pain (title/abstract).
#18 #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17.
#19 randomised controlled trials as topic (MeSH terms).
#20 randomised controlled trial (publication type).
#21 random* (title/abstract).
#22 trial (title/abstract).
#23 clinical (title/abstract).
#24 #19 OR #20 OR #21 OR #22 OR #23.
#25 #6 AND#18 AND#24.

MeSH, Medical Subject Headings.

Study selection

EndNote V.X9 will be used to manage the citations identified by our search strategy.[28] Two reviewers (CY and LH) will independently screen the eligibility of citation titles and abstracts, and then the full texts will be downloaded for further evaluation according to the inclusion criteria. Disagreements will be resolved by a third reviewer (MS). The selection procedure will be shown in a PRISMA flow chart (figure 1).

Data extraction and management

Two reviewers (XG and TH) will extract the relevant data independently from all eligible studies and enter them into a predefined Excel data collection form as described below:

1. General information: reference ID, author information, country, publication date, participant characteristics, number of centres, sample size, pain duration, study design.
2. Acupuncture intervention: type of acupuncture, acupoint selection, needling existing time, and acupuncture frequency/duration/session. Acupuncture technique details will be extracted based on the Standards for Reporting Interventions in Clinical Trials of Acupuncture checklist.[29]
3. Comparator: methods, dosage, frequency/duration/session, extracted according to the acupuncture interventions described above.
4. Mean value of pain intensity score and function score at baseline (pretreatment) and all available time points during the trial, adverse effects, medication intake and so on.

We will try to contact the corresponding authors for missing data or unclear information. For studies that report multiple pain intensity measures simultaneously, we will use the following order for extraction: VAS, NRS, SF-36 bodily pain, BPI, McGill and other measurement tools.[30]

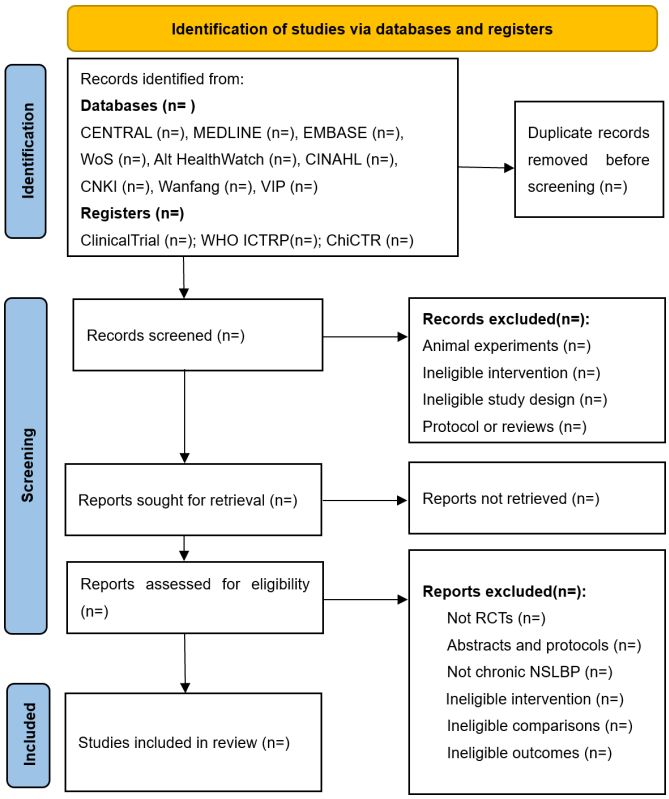

Figure 1 The selection process flow chart. Alt HealthWatch, alternative health research database; CENTRAL, Cochrane Central Register of Controlled Trials; CINAHL, Cumulative Index to Nursing & Allied Health Literature; CNKI, China National Knowledge Infrastructure; ChiCTR, Chinese Clinical Trial Register; NSLBP, non-specific low back pain; RCTs, randomised controlled trials; WHO ICTRP, WHO International Clinical Trials Registry Platform; WOS, Web of Science.

Risk of bias and confidence in the evidence

The risk of bias within all eligible studies will be assessed using the Cochrane Collaboration's Risk of Bias 2 Tool (RoB 2.0).[31] Two independent reviewers (QL and CY) will evaluate the risk of bias using the licensed Excel tool for implementation. The RoB outcomes will be graded by the following areas: sequence generation, allocation concealment, blinding, incomplete outcome data and selected outcome reporting. Each item will be rated as 'high risk', 'low risk' or 'some concerns' of bias. Additionally, the certainty of evidence will be assessed using the Confidence in Network Meta-Analysis (CINeMA) tool, accessed at https://cinema.ispm.unibe.ch/. QL and CY will independently evaluate the certainty of evidence and assign it a rating of 'high', 'moderate', 'low' or 'very low'.[32] If there are serious risks of bias, inconsistency or publication bias, the evidence level will be downgraded. Any disagreement between the assessment RoB and evidence certainty will be discussed and resolved with a third reviewer (MS).

Data synthesis and statistical analysis

Quantitative analysis will be conducted for pain intensity and physical function. We will perform a traditional pairwise meta-analysis for all direct comparisons, and the dose-response relationships between acupuncture sessions, durations and frequencies, and the improvement in pain intensity and physical function will be analysed using a Bayesian framework MBNMA.[25] We will convert the mean scores at different time points into change scores from the baseline, by subtracting baseline means from outcome means. SEs, CIs or p values will be converted into SD. To provide a more accurate clinical interpretation of the results, we will convert all outcome data for pain intensity and physical function to a scale of 0–100.[33] For example, a 0–10 VAS score is divided by 10 and multiplied by 100. Weighted mean differences with 95% CI will be calculated. The I^2 refers to the magnitude of heterogeneity. If I^2<50%, it will indicate heterogeneity is not prominent for the explored studies. Otherwise, the substantial heterogeneity will be analysed. Regardless of the I^2 value, the random-effects model will be selected for data analysis. The Egger's test will be used to test potential publication biases. The data will be modelled using recommended non-linear functions (Emax, restricted cubic splines) based on the observed shapes. According to the best-fitting model and biological plausibility, we will place three knots at the 10th, 50th and 90th percentile of the acupuncture time nodes. All analyses will be performed in R V.4.2.1 (R Core Team, 2022). In addition to the 'meta' package for effect sizes calculation (Hedges' g) and heterogeneity assessment, we will use the 'MBNMAdose' package to perform MBNMA and dose-response relationships, as well as the 'metacart' package for decision-trees meta-analysis modelling, and the 'ggplot2' package for dose-response curves plotting and visualisation. The subgroup analysis will be classified by different acupuncture types (manual acupuncture vs electroacupuncture). Sensitivity analyses will be performed to determine the robustness and quality of the results. The adverse effects of acupuncture and conventional therapy will be summarised descriptively and the safety between them will be compared.

Assumptions of transitivity and consistency

The transitivity will be assessed by checking the categorised characteristics: participant setting (inpatient or outpatient), pain intensity at baseline, needling existing time, participant age and sex. The network Global inconsistency and Local inconsistencies will be assessed by the design-by-treatment interaction model and Bucher method, respectively.[34 35] We will conduct a sensitivity analysis if Global inconsistency exists.

Patients and public involvement

No patients nor members of the public will be directly involved in this review.

DISCUSSION

Acupuncture, an ancient traditional Chinese medical therapy, has become one of the most popular complementary and alternative therapies worldwide since the 1970s.

In recent decades, more and more acupuncture clinical practices have emerged in both eastern and western countries. However, it seems the acupuncture efficacy in eastern countries such as China, Japan and Korea is consistently higher than in western countries.[36] The key issues might mainly surround the quality of acupuncture trial design and acupuncture intervention protocols.[37] Time dosing, including the retaining time, session, frequency and duration, is an important factor of acupuncture efficacy. However, the temporal parameters vary depending on the disease conditions. In clinical practice, the selection of acupuncture frequency, session and duration still lacks evidence-based medical support. Increasing acupuncture frequency will increase the cost of medical care, while decreasing the frequency may yield fewer benefits. Therefore, quantifying the optimal acupuncture timing parameters is of significant clinical value.

Chronic NSLBP is the top reason for seeking acupuncture treatment in America and over 10 million Americans are long-term opioid drug dependent, many because of chronic LBP.[38] The Lancet working group called for 'the need to avoid excessive medical solutions' and recommended relevant non-pharmacological integrative treatments.[3 39] As one dominant disease in acupuncture, chronic NSLBP was chosen to explore its optimum acupuncture time parameters for better medical outcomes.

NMA, which could integrate direct and indirect comparisons, is widely used to evaluate the comparative efficacy and safety of various acupuncture methods. MBNMA is a new Bayesian framework for NMA strategy to assess the dose-response relationship of acupuncture. Based on this review, it will help doctors and policymakers for better acupuncture time parameters setting. Finally, we sincerely hope for more studies on the dose-response relationship of acupuncture for different diseases, such as viscera or limbs diseases, and acute or chronic diseases. In this way, acupuncture time prescriptions in practice will be better quantified to achieve the MTB of acupuncture.

ETHICS AND DISSEMINATION

The results will be expected to be published in peer-reviewed journals or conferences. Additional ethical considerations were not posed by this secondary analysis. We will not endanger or compromise the privacy rights of participants.

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Contributors QL and CY contributed equally. QL and XG conceptualised this study. Under the supervision of MS and FL, QL and CY will formulate the protocol research and conduct the systematic review. Literature search, screening, data extraction and quality assessment will be performed by QL, CY, LH, XG and TH. The data will be analysed by QL and XG. The final protocol was drafted by all authors along with QL's first draft of the manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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ORCID iDs
Qin Luo http://orcid.org/0000-0002-3482-3799
Xu Guixing http://orcid.org/0000-0002-8040-3656
Mingsheng Sun http://orcid.org/0000-0002-6748-5087
Fan-rong Liang http://orcid.org/0000-0001-8518-9268

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