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STUDY PROTOCOL

Acupuncture for Pain and Function in Patients with Nonspecific Low Back Pain: Study Protocol for an Up-to-Date Systematic Review and Meta-Analysis

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Aim: To assess the pain and function of acupuncture in patients with nonspecific low back pain (NSLBP).

Design: This is a study protocol for an upcoming, updated systematic review and meta-analysis. We have registered on the PROSPERO platform, and the registration number is CRD42020149647.

Methods: We will identify studies in seven English databases, including Web of Science, Cochrane Library, CINAHL, Physiotherapy Evidence Database, Medline, Embase, and Scopus, and in four Chinese databases, including China National Knowledge Infrastructure (CNKI), China Biology Medicine disc (CBMdisc), Wanfang Database, and VIP database. We will also manually search key journals about acupuncture, the references of identified relevant trials, and the Clinical Trials Registry Platform. Different search strategies of Medical Subject Headings (MeSH) and non-MeSH terms will be applied alone or integrated. We will evaluate methodological quality by adopting Cochrane's risk of bias criteria and perform a meta-analysis using RevMan V.5.4 software.

Results: This study's results will be reported according to the PRISMA checklist and presented at an authoritative scientific conference or an authoritative scientific journal.

Keywords: acupuncture, nonspecific low back pain, protocol, update, meta-analysis

Introduction

Nonspecific low back pain (NSLBP) accounts for approximately 90% to 95% of patients with low back pain (LBP) and has become one of the most common conditions in the world.[1–3] NSLBP means that the pain in the lower back was not built by some definite pathological disorder such as cancers, viruses, bacteria, or fractures, but instead referred to as some puzzling etiology.[4] LBP is traditionally categorized into three phases, the pain first outbreak in the latest past one month is acute low back pain (ALBP), in the past two to three months is subacute low back pain, greater than past three months is chronic low back pain (CLBP).[5] Although most patients affected by ALBP experience a decrease in pain and disability within a month, studies show that a significant number of ALBP will develop into chronic pain, owing to the recurring nature of LBP.[6,7] Therefore, suffering from LBP may mean a lifetime of living with this symptom. In addition, LBP has become one of the most costly musculoskeletal problems to treat, ranking sixth in overall disease burden.[8]

Intervention strategies are commonly prescribed based on movement/pain relations due to LBP typical intermittency and periodicity.[5] Different strategies are also frequently applied, such as pharmacological treatment,[9] manual therapy,[10] therapeutic exercises,[11] and patient education.[12] Specifically, acupuncture is one of the most critical nonpharmacological treatments for back pain.[9,10] Several studies have evaluated the effect of acupuncture compared with other therapies, such

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as medication, sham acupuncture, placebo acupuncture, and conventional therapy,[13–16] but have not come to a consistent conclusion as to which therapy is most effective.

In our previous study,[17] we assessed the effects of acupuncture for NSLBP on the outcomes of pain and function and found that, for pain relief, acupuncture comes out to be prior to no treatment, sham acupuncture, and usual care in the short-term and intermediate-term, but for functional improvement, we found it difficult to draw a credible conclusion due to limited data. After this first systematic review in 2018, several studies of acupuncture for NSLBP have been published, and these will maybe provide new evidence for the effect of acupuncture on NSLBP. Therefore, this study is aimed to provide a protocol for an upcoming, updated systematic review and meta-analysis, which will synthesize the latest research findings on acupuncture on NSLBP pain relief and back-related dysfunction improvements.

Materials and Methods

Study Registration

This protocol is reported based on the guideline of Preferred Reporting Items for Systematic Reviews and Meta-analyses Protocols (PRISMA-P) 2015.[18] This study has been registered on the PROSPERO website, an international database of prospectively registered systematic reviews, and our registration number is CRD42020149647.

Inclusion Criteria

Types of Studies

Our upcoming review will only include randomized controlled trials (RCTs) for NSLBP treated with acupuncture. We will exclude RCTs that compare different types of acupuncture and RCTs that compare different treatment session numbers. Furthermore, we will search the literature without restriction to region or publication type.

Types of Participants

Our upcoming review will exclude animal studies and include studies with only adult subjects (over 18 years old) with NSLBP. The LBP in this study is defined as the pain at the 12th rib and the inferior gluteal fold,[6,19] including the radiate pain and neurological symptoms in the legs.[6] NSLBP refers to LBP when there are no known definitive pathoanatomical causes after radiological diagnoses.[20]

We will include patients with NSLBP irrespective of pain duration (acute, subacute, or chronic). The type of age, sex, and race of enrolled participants is not restricted in this study.

Types of Interventions

Experimental Interventions

We will consider all clinical trials that use acupuncture as an intervention for NSLBP in our study, including traditional acupuncture, in which needles were inserted in classical meridian points, or contemporary acupuncture, in which the needles were inserted in non-meridian or trigger points.[21] We will exclude studies that do not use needles, such as acupressure, laser acupuncture, point injection, or tap-pricking, and those that compare different acupuncture methods. This study will not limit the duration of intervention sessions and the length of intervention periods.

Comparator Interventions

We will consider methods such as no intervention, sham acupuncture, placebo acupuncture, and usual care for control interventions. Sham acupuncture is defined as the needle is not directly inserted into the meridian points but placed in a close area,[22] or using the electrodes to stimulate the skin.[23] Placebo acupuncture means the needle touches the skin surface at meridian points but does not penetrate the skin,[22] and usual care is refers to medication or physiotherapy, such as rehabilitation training and exercise. We will exclude trials where a control intervention included acupuncture plus another treatment or where a control intervention was surgery.

We will investigate the comparisons listed below: acupuncture vs no treatment; acupuncture vs sham acupuncture; acupuncture vs placebo acupuncture; acupuncture vs usual care; acupuncture plus usual care vs sham acupuncture; acupuncture plus usual care vs placebo acupuncture; acupuncture plus usual care vs usual care.

Types of Outcome Measures

Primary Outcome

The primary outcome of this study will be pain intensity. In order to provide comprehensive and systematic results, we will include and extract all the assessment tools and related scores if the original study employed this indicator. The possible inconsistency of different questionnaires will be resolved by subgroup analysis and statistical analysis. The possible assessment tools in original studies may be a visual analogue scale (VAS), McGill pain questionnaire, Von Korff chronic pain grade score, 11-point numeric rating scale, or proportion of pain relief patients.

Secondary Outcome

The secondary outcome of this study will be back pain-related function status, which may be measured by the Roland-Morris disability questionnaire, Oswestry disability index, Hanover Functional Ability Questionnaire, modified Aberdeen LBP Scale, or the fingertip-to-floor distance indicated lumbar flexibility.

If available, the motion of joints and quality of life will also be selected as secondary outcomes. In addition, the number of adverse events will be recorded, and the proportion of different kinds of adverse events of each type of comparison treatment will be calculated.

Outcome Measurement

We categorize the period of NSLBP as three phase: (1) acute NSLBP (pain onset< 1 month); (2) subacute NSLBP (pain onset between 1 and 3 months); and (3) chronic NSLBP (pain onset > 3 months) and define the follow-up time points as four terms: (1) immediate-term (post intervention < 1 week); (2) short-term (post intervention between 1 week to 3 months); (3) intermediate-term (post intervention between 3 and 12 months); and (4) long-term (post intervention > 1 year).

Search Strategy

Electronic Searches

To identify eligible studies, we will conduct our main search in seven English databases, including Web of Science, Cochrane Library, CINAHL, Physiotherapy Evidence Database, Medline, Embase, and Scopus, and in four Chinese databases, including China National Knowledge Infrastructure (CNKI), China Biology Medicine disc (CBMdisc), Wanfang Database, and VIP database. Different search strategies of Medical Subject Headings (MeSH) and non-MeSH terms will be applied alone or integrated. The search terms were: “acupuncture” OR “electro-acupuncture” OR “ear acupuncture” OR “hand acupuncture” AND “lower back” OR “lumbosacral region” OR “low back pain” OR “LBP” OR “lumbago” OR “back strain” OR “lumbar back sprain” OR “nonspecific low back pain” OR “NSLBP” OR “myofasciitis” OR “lower spine disease”.

The search strategy was developed according to critical terms from literature reviews on the subject. The search strategy will include all search terms and other searches based on those results. Specific search terms will be adapted according to the databases necessary, and the search for study dates will not be restricted.

Searching Other Resources

Key journals about acupuncture, the references of identified relevant trials, and Google Scholar will be manually searched to identify additional studies or any grey literature. The Clinical Trials Registry Platform will also be manually searched to check planned, ongoing, or unpublished trials. In addition, other language reports will be screened to identify if there are any available English or Chinese abstract.

Data Collection

Selection of Studies

Only RCTs will be considered in this study. Two reviewers will screen the eligibility of studies. Titles and abstracts will be first screened, and if it meets our predefined inclusion criteria, the full texts will be further downloaded and screened. Any discrepancy about inclusion that may arise between two reviewers will be consulted by the third author that not screen the initial studies. We will employ Endnote software to manage the study records and the latest PRISMA flow chart to show the selection process (Figure 1).[24]

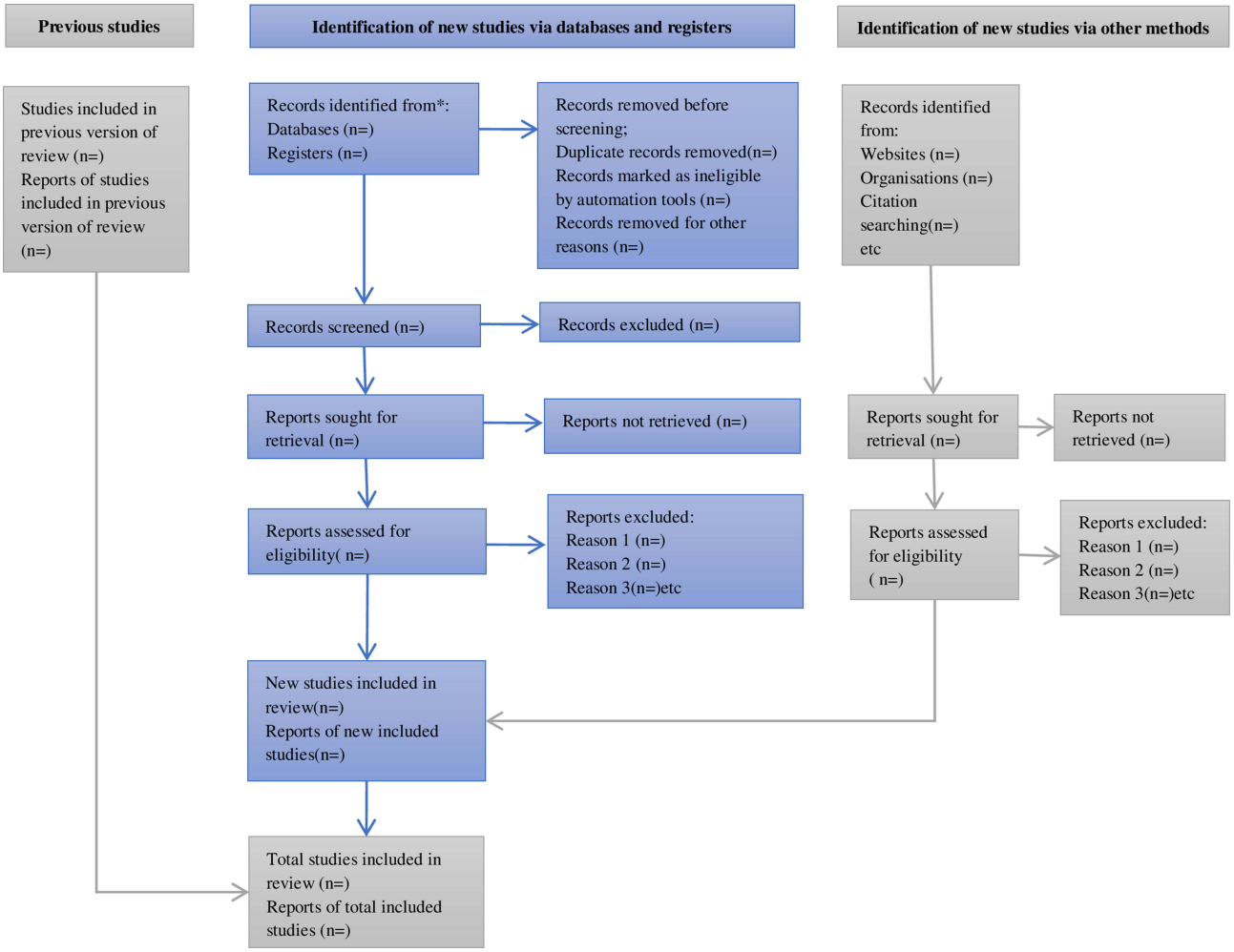

Figure 1 The PRISMA flow chart of the selection process.
Note: PRISMA figure adapted from Page MJ, Moher D, Bossuyt PM, et al.PRISMA 2020 explanation and elaboration: updated guidance and exemplars for reporting systematic reviews. *BMJ*. 2021; 372: n160. Creative Commons.[24]

Data Extraction and Management

Two evaluators will extract the data from included studies individually. A self-designed data collection table based on the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) checklist will be used.[25] Before data extraction begins, we will conduct adjustment exercises to secure evaluators' consistency.

The data collection will be performed by using three tables. Supplementary Table 1 will be used to collect the general characteristics of the included studies, which include two parts. Part one is the study characteristics such as title, authors, journal, year of publication, country of study, and registry number. Part two is participants' characteristics, such as age, sex, sample size, the number for analysis, duration of LBP, inclusion criteria and exclusion criteria. Supplementary Table 2 will be used to collect the included studies' specific characteristics and consists of three parts. Part one is the design characteristics, such as purpose, design, randomization, allocation, and blinding. Part two is intervention characteristics, including group, type, frequency, and length. Finally, Part three is the outcomes and measurements, including primary and secondary outcomes, the outcome assessment indicators, follow-up time points, drop-out rates, and adverse effects.

Supplementary Table 3 will be used to collect the data for RevMan. For measurement data, mean (M), standard deviation (SD), and total participants' number will be extracted; For enumeration data, the events number and the total

participants' number will be extracted. Only the most relevant two arms data will be extracted for more than two arms studies. If necessary, an attempt to contact the original authors will be made for missing values.

Assessment of Risk-of-Bias in Included Studies

Two authors will independently assess the risk of bias in included studies, and a classic risk-of-bias tool recommended by the Cochrane Handbook for Systematic Reviews of Interventions will be used.[26] The following seven domains will be critically evaluated to find potential biases: sequence generation and allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, and selective outcome reporting.

In included studies, every domain will be judged for low risk of bias, unclear risk of bias, or high risk of bias via a carefully investigate of what is reported and performed in each original study. And then, the overall risk of bias in individual studies will be comprehensively classified according to the number of low-risk bias domains, and if all domains are at low risk of bias, the individual study will be categorized as a low risk of bias study. Otherwise, the individual study will be categorized as a high risk of bias study.[27] As above, a third author will participate in the discussion if there are any discrepancies between the two authors. The risk-of-bias will be presented as a risk of bias summary and risk of bias graph individually.

Data Analysis

Measures of Treatment Effect

For a specific comparison, for continuous data, effects size will be represented by weighted mean difference (WMD) and its 95% confidence interval (95% CI) if the assessment tools were the same across the original studies; While, standardized mean differences (SMD) and its 95% CI will be computed if the assessment tools were different across the original studies.[28] For dichotomous data, effects size will be estimated by the risk ratio (RR) with a 95% CI.[29]

Dealing with Missing Data

The original study's first author or correspondence author will be first contacted through the articles attached emails if the needed data is not reported in the manuscript. Whereas, if additional information fails to be obtained, only the available data will be analyzed, and the potential impact will be interpreted in the discussion part.

Assessment of Heterogeneity

Statistical heterogeneity, clinical heterogeneity and methodological heterogeneity will be assessed in our review. The statistical heterogeneity will be evaluated using an I^2 test and $\chi 2$ tests. If $p < 0.1$ for the $\chi 2$ test or if $I^2 > 50\%$ will be considered statistically significant heterogeneity.[30] If $p > 0.1$ and $I^2 < 50\%$, fixed effect models will be adopted in our meta-analysis. Otherwise, if $p < 0.1$ and $I^2 > 50\%$, the random-effects model will be used, and subgroup analysis will be employed to analyze the potential heterogeneity from clinical or methodological.[30]

Assessment of Reporting Biases

Reporting Biases will be assessed if the analyzed trials number is greater than 10, and funnel plots will be used to present the publication bias graphically.[31] Possible interpretations will be discussed in the discussion section.

Data Synthesis

If more than one RCT evaluated the same intervention and outcomes with comparable methods in similar subjects, quantitative synthesis, the meta-analysis, will assess the pooled intervention effect size.[32] In meta-analysis, different effect models (fixed or random) will be used for data synthesis according to the heterogeneity results. All meta-analyses will be performed using Review Manager Software Version 5.4. Otherwise, if the meta-analysis is inappropriate, we will only conduct a narrative synthesis and summarize the essential information of individual original included studies.

Subgroup Analysis and Investigation of Heterogeneity

If there is an extensive enough number of statistically significant and clinically heterogeneous RCTs, we will carry out subgroup analyses. For categorical variables, acupuncture methods, acupuncture points, NSLBP stages, post-intervention stages, and assessment tools will be considered for subgroup analyses. For continuous variables, mean age will be used as a primary dimension to perform meta-regression at each time point if available.

Sensitivity Analysis

If quantitative synthesis is conducted, the sensitivity analysis will also be performed to examine the robustness of the pooled meta-analysis results. We will re-perform a meta-analysis to observe whether the in point estimates and interval estimates of the combined values of effects changed by using different effect models, removing low-quality literature, deleting small sample size studies, or changing inclusion and exclusion criteria. We will then compare the results and report all results of sensitivity analyses in the main text and explain the possible causes in the discussion section to analyze how the issue of inconsistency was resolved and if it was fully resolved or not.

Summary of Cumulative Evidence

We will adopt the Grading of Recommendations Assessment, Development and Evaluation profiler (GRADEpro) Guideline Development Tool (https://gradepro.org) to grade the overall quality of the body of evidence for each outcome according to five criteria: study limitations, imprecision, inconsistency, indirectness, and publication bias, and the evidence will be divided into four levels: high, moderate, low, or very low.[33] High quality refers to further research that is unlikely to change our confidence in the estimate of effect. Moderate quality refers to further research that significantly impacts our confidence in estimating effect and may change the estimate. Low quality means further research is very likely to have a meaningful impact on our confidence in the estimate of effect and is likely to change the estimate. Very low quality means we are very uncertain about the estimate.[34]

Amendments

If there is any amendment to the protocol, we will illustrate the rationale for amendments and present the date and the change in the main text.

Ethics and Dissemination

Because this will be a secondary analysis of primary studies, no patients and no public participants will be involved, and no primary data will be collected, ethical approval is not required. This review will provide the latest RCTs evidence respecting the effects of acupuncture on NSLBP. The conclusions may provide essential reliable evidence for NSLBP treatment and research in future. This study's results will be reported according to the PRISMA checklist and presented at an authoritative scientific conference or an authoritative scientific journal.

Discussion

We applied systematic review and meta-analysis to assess the effectiveness of acupuncture for NSLBP by including the latest RCTs. This upcoming study will provide comparisons of acupuncture with other interventions such as no treatment, sham acupuncture, and usual care in pain and function of NSLBP.

Recently, evidence shows that acupuncture is superior to other types of treatment for LBP to some extent.[35–37] However, the duration of the effects after acupuncture intervention remains unclear, and the quality of evidence from each study is not graded. Our upcoming study will provide a broad summary of trials evaluating the effectiveness of acupuncture for NSLBP at different post-intervention time points, if available, and will also grade the evidence quality for primary and secondary outcomes.

The strength of this study was that first, this review was reported according to the PRISMA-P, and the upcoming study will conduct according to the STRICTA checklist and PRISMA guidelines. Second, to ensure good literature, we will search seven primary English and four Chinese databases, and a manual search will also be conducted in crucial journals of acupuncture and clinical trials registry platform. Third, we will only include the "gold standard" of clinical

trials -RCT- to get relatively reliable conclusions. Fourth, our study will provide a comprehensive comparison of the effect of acupuncture on NSLBP and will provide subgroup analysis according to acupuncture methods, acupuncture points, NSLBP stages, post-intervention time points, and assessment tools, if available. Finally, we will grade the overall quality of the evidence for each outcome, which may help clinicians make treatment decisions.

However, we also must mention the limitations of the upcoming study. First, the definition of "usual care" intervention is frequently ambiguous in individual studies, making it challenging to design subgroup analysis. Second, the accuracy of the meta-analysis pooled results will mostly rely on original study quality and clinical heterogeneity across studies, especially crucial information about design (such as random sequence generation, allocation concealment and blinding methods) and intervention program details (such as intervention sessions and length, and outcome assessment tools).

Given the potential bias across different original studies, we could only provide a cautious conclusion in this upcoming study. We thus recommend that RCTs with more standard intervention and higher quality are needed in future to validate these findings. Additionally, although we will perform meta-analyses according to different acupuncture methods (traditional or contemporary acupuncture), we cannot get the results of optimal acupuncture methods and optimal treatment session number. Therefore, systematic reviews and network meta-analyses are needed to compare different acupuncture methods and treatment sessions, and stronger head-to-head RCT is also needed to confirm the corresponding conclusions in the future.

Conclusions

Our updated study will synthesize the latest evidence of the effect of acupuncture on NSLBP. It will summarize the effect of acupuncture according to different acupuncture methods, acupuncture points, duration of back pain, follow-up time intervals, and measurement tools for the same outcomes. The results from the study will demonstrate the effects of acupuncture on specific outcomes and then provide evidence that can be useful for developing acupuncture programs in clinical practice. In addition, this study will also provide references for designing further studies as a difference between research and practice may be displayed in the upcoming study.

Abbreviations

NSLBP, Nonspecific Low Back Pain; LBP, Low Back Pain; ALBP, Acute Low Back Pain; CLBP, Chronic Low Back Pain; RCTs, Randomized Controlled Trials; PRISMA-P, Preferred Reporting Items for Systematic Reviews and Meta-analyses Protocols; CNKI, China National Knowledge Infrastructure; CBMdisc, China Biology Medicine disc; MeSH, Medical Subject Headings; STRICTA checklist, Standards for Reporting Interventions in Controlled Trials of Acupuncture checklist; M, Mean; SD, Standard Deviation; WMD, Weighted Mean Difference; 95% CI, 95% Confidence Interval; SMD, Standardized Mean Differences; RR, Risk Ratio; GRADEpro, Grading of Recommendations Assessment, Development and Evaluation profiler.

Reporting Checklist

The authors have completed the PRISMA-P reporting checklist.

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Author Contributions

All authors contributed to data analysis, drafting or revising the article, have agreed on the journal to which the article will be submitted, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

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Disclosure

The authors have no conflicts of interest related to this work.

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