INPLASY PROTOCOL

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None declared.

Dry needling for low back pain: A Protocol for a Systematic Review and Meta-Analysis

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Review question / Objective: **The aim of this study is to provide evidence for the effectiveness and safety of integrated therapies. This article describes the protocol for the methods that will be applied in our systematic review.**
Condition being studied: **Low back pain (LBP) is very common and poses a great health risk for society.Worldwide, it is the number one cause of years lived with disability.There are substantiate numbers of populations suffering from low back pain, with an estimated 33% point prevalence, 65% 1 -year prevalence, and 84% lifetime revalence.LBP is strongly associated with disability , work absence, and reduced quality of life.Most patients improve substantially in the first six weeks after the onset of LBP. However, one year after onset, approximately two thirds of patients still experience pain and disability.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 totreat, ranking sixth in overall disease burden.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 August 2022 and was last updated on 13 August 2022 (registration number INPLASY202280045).

INTRODUCTION

Review question / Objective: **The aim of this study is to provide evidence for the effectiveness and safety of integrated therapies. This article describes the protocol for the methods that will be applied in our systematic review.**

Rationale: **LBP is very common and poses a great health risk for society.Worldwide,it is the first cause of years lived with disability.There are substantiate numbers of populations suffering from low back pain, with an estimated 33% point prevalence, 65% 1-year prevalence, and 84% lifetime prevalence.Currently, there is not an universally accepted evidence-**

based treatment approach that has been recommended for patients with LBP.

Condition being studied: Low back pain (LBP) is very common and poses a great health risk for society.Worldwide, it is the number one cause of years lived with disability.There are substantiate numbers of populations suffering from low back pain, with an estimated 33% point prevalence, 65% 1 -year prevalence, and 84% lifetime revalence.LBP is strongly associated with disability , work absence, and reduced quality of life.Most patients improve substantially in the first six weeks after the onset of LBP. However, one year after onset, approximately two thirds of patients still experience pain and disability.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 totreat, ranking sixth in overall disease burden.

METHODS

Search strategy: Different search strategies of Medical Subject Headings (MeSH) and nonMeSH terms will be applied alone or integrated. The search terms were: “dry needling ” OR “trigger point acupuncture” OR “Muscular needling” OR “Intramuscular stimulation” 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” OR“low backache”OR “sciatic neuropathy” OR “coccydynia” OR “lumbar radicular pain” AND “ Myofascial Pain Syndromes” OR “ trigger points " OR “trigger point” .

Participant or population: Inclusion criteria:1.Adult Participants with LBP as well as the presence of MTrPs were included. The LBP in this study is defined as the pain at the 12th rib and the inferior gluteal fold. Patients with (sub)acute (12 weeks) or chronic low back pain (greater than12 weeks) were included.2.Participants whose symptoms were discomfort and pain positioned below the costal margin and above the subgluteal fold, regardless of primary or secondary and with or without associated leg pain, were included.Exclusion criteria:1.Participants with LBP caused by pathologic entities such as infection, metastatic diseases, neoplasm, or fractures were excluded.2.Participants whose LBP was associated with pregnancy and parturition were also excluded.3.Patients received any acupuncture therapy that allows the muscular insertion and stimulation of needles within 6 month.

Intervention: All trials evaluating dry needling intervention will be included. In addition, RCTs involving DN combined with another therapy were also included if that adjuvant therapy was the same in both experimental and control groups. Acupuncture was excluded.

Comparator: We will consider methods such as no intervention, sham dry needling and placebo dry needling for control interventions.

Study designs to be included: Only randomized control trials (RCTs) will be included (with or without blinding, including crossover designand pragmatic trials) if they aim to investigate the efficacy of dry needling for low back pain. Case series, reviews and other types of non-randomized controlled trials will be excluded.

Eligibility criteria: Trials of low back pain due to other pathologies such as fibromyalgia, tumor, compression fracture, infection, trauma, cauda equine syndrome, vertebral canal stenosis, scoliosis or ankylosing spondylitis will be excluded.

Information sources: We will search the following electronic databases from their inception to June 2022:PubMed, PEDro, Embase, Ovid, Web of Science, Cochrane, CINAHL ,ScienceDirect, China National Knowledge Infrastructure(CNKI), Chinese Biomedical Literature Database (CBM) , the Wanfang database and VIP database. No language restrictions were placed on the search of articles.

Main outcome(s): Pain intensity and functional status/disability will be the primary outcome 1.Pain intensity will be evaluated using the visual analogue scale (VAS), McGill pain questionnaire, Von Korff chronic pain grade score, 11-point numeric rating scale, or proportion of pain relief patients. 2.Functional status/disability will be evaluated using validated measurement tools such as the Roland Morris Disability Questionnaire (RMDQ), the Oswestry disability index (ODI), or Hanover Functional Ability Questionnaire.

Additional outcome(s): Health-related physical and mental quality of life, work disability, frequency of analgesic use and adverse events will be the secondary outcome. 1.Quality of life (QOL) measured by standardized questionnaires with established validity, such as the Short Form 36 (SF-36). 2. Work disability. 3. Frequency of analgesic use or the number of medications used. 4. Adverse events.

Data management: After conducting the search procedure, two researchers (HJH and ZCY) will independently complete the screening procedure. First, overlapping studies will be excluded. Subsequently, the remaining studies will be excluded based on our assessments of the abstract, title, and full text.The following data will be extracted: article title, first author's name, corresponding author, journal's name, year of publication, contact information, country of study, size of the sample, registry number, inclusion criteria and exclusion criteria, age, sex, race, sample size, the number for analysis, duration of LBP and diagnostic criteria for LBP.Data extraction was also conducted by consensus. If disagreement occurred, a third author participated.

Quality assessment / Risk of bias analysis: Two authors(HJH and ZCY)will independently assess the risk of bias in included studies, and a classic riskof-bias tool recommended by the Cochrane Handbook for Systematic Reviews of Interventions will be used.This tool includes six domains: random sequence generation, allocation concealment, blinding of participants, blinding of outcome assessment, selective outcome reporting, and incomplete outcome data.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 (Y Suai) will make the final decision.

Strategy of data synthesis: We will use Review Manager Software Version 5.4 to perform the meta-analysis. 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 will not be able to conduct a meta-analysis because of a lack of clinical studies or because of heterogeneity, we will present the effect size and 95% CI of every outcome in each clinical trial and describe the significance of important results in the results section.

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) Duration of follow-up (i.e., short, medium, and long term); (3) treatment number, frequency, and duration.

Sensitivity analysis: We will conduct a sensitivity analysis to identify the robustness of the results. The methodological quality will be assessed using the risk-of-bias tool. According to this procedure, low-quality trials will be excluded and a second meta-analysis will be conducted.The results and effect size of the two meta-analyses will be compared and discussed.

Language restriction: English.

Country(ies) involved: China.

Keywords: dry needling , low back pain, protocol, meta-analysis.

Dissemination plans: This protocol outlines the planned scope and methods for an upcoming systematic review meta-analysis, which aims to evaluate the effects of DN therapy application on pain intensity, physical function, quality of life and psychological symptoms which cause a negative impact on the quality of life in these individuals with LBP compared with a placebo group.

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