INPLASY PROTOCOL

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None declared.

Study on manual therapy in the treatment of low back pain based on rs-fMRI: a protocol for systematic review and meta-analysis

Zhou, XC[1]; Lv, ZZ[2]; Lv, LJ[3].

Review question / Objective: **This study was conducted in order to investigate the study design and main outcomes of manual therapy neuroimaging studies on low back pain(LBP),and reveal the potential mechanism of the painrelieving effect of manual therapy on low back pain.**
Condition being studied: **Studies have shown that manual therapy (MT) has significant therapeutic effects on low back pain (LBP). However, the exact mechanisms of action underpinning these effects remain controversial, especially in brain mechanisms. Resting-state functional MRI (rs-fMRI) is an advanced imaging technique that can be used to monitor changes in the activity of the brain. Therefore, rs-fMRI is widely used to study the brain mechanism of manual therapy for LBP, and related research evidence is also emerging. Whereas, the data from several studies remain inconclusive, and there is currently no systematic review and meta-analysis for the use of rs-fMRI in LBP.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 August 2022 and was last updated on 02 August 2022 (registration number INPLASY202280008).

INTRODUCTION

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METHODS

Participant or population: We will include RCTs of adult subjects defned as aged 18 years or older who have acute, subacute, or chronic nonspecifc low back pain with or without sciatica. We will include RCTs that include participants of any gender and race/ethnicity, any duration of illness, and any previous treatment. We will exclude RCTs that include patients with specifc low back pain caused by pathological entities such as infection, neoplasm, metastasis, osteoporosis, rheumatoid arthritis, cauda equina syndrome, or fractures. We will also exclude RCTs with pregnant or postpartum subjects.Patients with low back pain.

Intervention: The eligible intervention is manual therapy, is a skilled hand manipulation, including massage, chiropractic, osteopathy, mobilization, spinal anipulation, myofascial release, Tuina, Shiatsu, etc.

Comparator: Controlled interventions included control groups with no treatment, sham/placebo groups, or other conventional treatments.

Study designs to be included: The review will include all clinical trials to investigate the central mechanism of manual therapy in the treatment of LBP based on rs-fMRI using ALFF, ReHo or FC as the main outcomes. Other experiments, such as non-clinical trials, noncontrolled trials will not be included.

Eligibility criteria: (1) randomized controlled trial; (2) patients with LBP; (3) using manual therapy; (4) outcomes should include neuroimaging studies.

Information sources: Pubmed, Embase, Cochrane Library, Chinese Biomedical Literatures Database(CBM), China National Knowledge Infrastructure (CNKI), WangFang Database(WF), Chinese Scientifific Journal Database (VIP).

Main outcome(s): The main outcomes will include the ALFF, ReHo, FC of the brain, the visual analog scale (VAS), the Japanese Orthopaedic Association scores (JOA), the Neuropathic Pain Symptom Inventory (NPSI), the Brief Pain Inventory (BPI) and the McGill Pain Questionnaire.

Quality assessment / Risk of bias analysis: Two of our researchers will use the bias risk tool provided by the Cochrane Collaboration to evaluate the quality of the literature using RevMan 5.4 software. This recommended tool includes 7 important items: sequence generation, allocation concealment, blinding of participants and personnel, blinding of results evaluation, incomplete result data, selective result reporting, and other biases. Make “Low risk,” “High risk,” and “unclear risk” judgments for each research literature. Finally, a “risk of deviation” summary and a chart are generated to show the results. As with the previous process, it will be independently assessed by 2 researchers. If there is disagreement, it will be discussed with the 3rd researcher.

Strategy of data synthesis: This study will use RevMan5.4 software for data integration and analysis. The measurement data will use the mean difference (MD) as the effect indicator, and the count data will use the odds ratio (OR) as the effect index. Each effect indicator will be given as a point estimate with 95% confifidence interval.The heterogeneity and size of each study result will be judged using statistical methods. For studies with no statistical

heterogeneity, the analysis will be performed using a fixed-effect model, whereas a randomized effects model will be applied if for studies with significant statistical heterogeneity.

Subgroup analysis: We will do subgroup analysis if necessary.

Sensitivity analysis: To assess the influence of each individual study, leave-one-out sensitivity analysis was performed iteratively by removing one study at a time to confirm that the findings were not influenced by any single study.

Language restriction: No restriction.

Country(ies) involved: China.

Keywords: manual therapy; low back pain; magnetic resonance imaging.

Contributions of each author:

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