INPLASY PROTOCOL

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The authors have no conflicts of interest to disclose.

The Effectiveness of Acupuncture in primary osteoporosis pain: a protocol for systematic review and meta-analysis

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Review question / Objective: **This study will evaluate the efficacy and safety of acupuncture treatment for POPP, to provide an important reference for clinical evidence-based.**
Condition being studied: **Acupuncture has currently received increasing attention as a treatment for primary osteoporosis pain (POPP). A large number of randomized controlled trials (RCTs) have shown that acupuncture have some advantages in treatment of POPP. However, its relative effectiveness have not yet been confirmed.**
Information sources: **We will search for PubMed, Embase, Cochrane Library, CNKI, WF, VIP, CBM literature databases from its inception to October 2020 with a language restriction on Chinese or English.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 December 2020 and was last updated on 05 December 2020 (registration number INPLASY2020120032).

INTRODUCTION

Review question / Objective: **This study will evaluate the efficacy and safety of acupuncture treatment for POPP, to provide an important reference for clinical evidence-based.**

Condition being studied: **Acupuncture has currently received increasing attention as a treatment for primary osteoporosis pain**

(POPP). A large number of randomized controlled trials (RCTs) have shown that acupuncture have some advantages in treatment of POPP. However, its relative effectiveness have not yet been confirmed.

METHODS

Search strategy: We will search for PubMed, Embase, Cochrane Library, CNKI, WF, VIP, CBM literature databases from its inception to October 2020 with a language restriction on Chinese or English.

Participant or population: Patients with primary osteoporosis pain (POPP).

Intervention: The experimental group was treated with acupuncture for primary osteoporosis.

Comparator: The control group was treated with traditional Chinese medicine or western medicine.

Study designs to be included: Randomized Controlled Trials (RCTs).

Eligibility criteria: All randomized controlled trials (RCTs) of acupuncture therapy for POPP will be included in the study, while animal experiments, cluster RCTs, reviews, and case reports will be excluded. The literary language types are limited to Chinese and English.

Information sources: Four Chinese electronic databases (China National Knowledge Infrastructure, Chinese Biological and Medical Database, China Scientific Journal Database, Wan-Fang Data) and three English electronic databases(PubMed, Embase, Cochrane Library) will be searched from their inception to 31 October 2020.RevMan 5.3 software and Stata 15.0 software will be used for meta-analysis.

Quality assessment / Risk of bias analysis: Two authors (WXL and WWH) independently evaluated risk of bias in the included RCTs. The methodological quality evaluation of the included studies according to the "risk of bias assessment" recommended by Cochrane Handbook 5.3,which includes 7 items as following: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, other bias.

Strategy of data synthesis: When more than 2 documents are included, RevMan 5.3 software is used for meta-analysis. Count data is expressed by relative risk (RR) and its 95% CI. For the same variable in measurement data, if the same measurement is used, then the weighted mean difference (WMD) and its 95% CI are used for analysis; Point inconsistency or mean or standard deviation between included studies When the difference is more than 10 times, the standard mean difference (SMD) and its 95% CI analysis are used.

Subgroup analysis: Two authors (WXL and WWH) independently evaluated risk of bias in the included RCTs. The methodological quality evaluation of the included studies according to the "risk of bias assessment" recommended by Cochrane Handbook 5.3, which includes 7 items as following: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, other bias. We will rate each domain as low, unclear, or high risk of bias. The studies will be evaluated as being of "low risk of bias"、"high risk of bias" or "unclear risk of bias" . At the same time, the included clinical trials will be awarded a score from 0 to 7 points according to Jadad scale evaluation criteria, which include reference to the generation of random sequences, blind enforcement, and withdrawal.

Sensibility analysis: If the heterogeneity is significant, we will conduct a sensitivity analysis according to eliminating each of the included studies one by one, and changing the effect scale of studies to evaluate the robustness and quality of the conclusion in the studies.

Language: Language restriction on Chinese or English.

Country(ies) involved: China.

Keywords: acupuncture, primary osteoporosis pain, systematic review, meta-analysis, protocol.

Dissemination plans: The final systemic review results will be submitted to a recognized journal for publication.

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