INPLASY PROTOCOL

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None.

Acupuncture and moxibustion for the prevention and treatment of postmenopausal osteoporosis: a protocol for a systematic review and meta-analysis

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Review question / Objective: **Osteoporosis is defined as a bone disease characterized by impaired bone strength, which is prone to increase bone fragility and the risk of fractures. PMOP is considered as a major public health issue for elderly women because fractures related to post-menopausal bone loss will reduce women's quality of life and may require hospitalization. Furthermore, PMOP in women is an irreversible process. Once it occurs, there is no obviously effective medicine to restore the lost bone mass. Treating the spleen and kidney simultaneously is the core treatment concept for PMOP. In addition, stimulating the acupoints of strengthening the spleen and kidney can control the development of postmenopausal osteoporosis, which embodies the idea of preventive treatment of existing disease. Hence, it is necessary to conduct a comprehensive review which is based on the theory of preventive treatment for disease to evaluate the efficacy and safety of acupuncture and moxibustion for treating PMOP.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 December 2020 and was last updated on 13 July 2021 (registration number INPLASY2020120131).

INTRODUCTION

Review question / Objective: **Osteoporosis is defined as a bone disease characterized by impaired bone strength, which is prone to increase bone fragility and the risk of fractures. PMOP is considered as a major public health issue for elderly women because fractures related to post-menopausal bone loss will reduce women's quality of life and may require hospitalization. Furthermore, PMOP in**

women is an irreversible process. Once it occurs, there is no obviously effective medicine to restore the lost bone mass. Treating the spleen and kidney simultaneously is the core treatment concept for PMOP. In addition, stimulating the acupoints of strengthening the spleen and kidney can control the development of postmenopausal osteoporosis, which embodies the idea of preventive treatment of existing disease. Hence, it is necessary to conduct a comprehensive review which is based on the theory of preventive treatment for disease to evaluate the efficacy and safety of acupuncture and moxibustion for treating PMOP.

Condition being studied: PMOP is the type 1 osteoporosis, which is mainly due to the lack of estrogen after menopause. Additionally, the deficiency of estrogen can break the dynamic balance between osteoclast bone resorption and osteoblast bone formation and it can result in progressive bone loss. PMOP have caused great damage to elderly women and the society and great importance should be attached to preventing and treating PMOP. As an important part of traditional Chinese medicine, acupuncture and moxibustion have attracted more and more attention during the treatment of many diseases.For patients with PMOP, the most direct effect of acupuncture and moxibustion is reflected in the changes in bone morphology and bone biomechanics, which mainly includes the increase of the bone density, bone mineral content and the number of bone trabeculae. To sum up, acupuncture and moxibustion therapy based on preventive treatment for disease theory may provide clinicians with simple and safe options for preventing and treating PMOP.

METHODS

Search strategy: Acupuncture and moxibustion prevention and treatment for PMOP in clinical trials will be searched in the following databases: the Cochrane Central Register of Controlled Trials, PubMed, EMBASE, the Web of Science, China National Knowledge Infrastructure (CNKI), Wan-Fang Database, Chinese Scientific Journal Database(VIP database) and Chinese Biomedical Literature Database (CBM).And our retrieval will conduct from inception to December 2020.Searching terms are a combination of subject terms and free words and we will change the corresponding search strategy for each database. Furthermore, the search strategy does not impose restrictions on publication types.We will try our best to search more relevant literatures including unpublished research results and trial registers.In order to obtain a more comprehensive and systematic conclusion, the research will be re-run if there are updated literatures.

Participant or population: The study is supposed to include postmenopausal women with a clear diagnosis of osteoporosis or female patients who have some symptoms or abnormal laboratory indicators related to osteoporosis but not up to the diagnostic criteria, regardless of their age, ethnicity, education, social status.

Intervention: The treatment used in the experimental group mainly includes acupuncture, electroacupuncture, warm acupuncture, stick-moxibustion, direct-moxibustion and partition moxibustion. Additionally, it can be a combination with pharmacotherapies. More importantly, the experimental group should include acupoints for strengthening the spleen and kidney such as BL20, BL23, CV4, ST36.

Comparator: The control group can be no treatment, sham acupuncture, conventional western medicines, Chinese patent medicine or acupuncture stimulation on acupoints that can't reflect the principle of tonify the spleen and kidney. What's more, if the experimental group is a combination of acupuncture and medicine, then the control group should adopt that kind of medicine.

Study designs to be included: The review will include randomised controlled trials (RCTs) that were reported in English or

Chinese. Non RCTs reviews, animal experimental studies, case report, expert experience and conference article will be excluded.

Eligibility criteria: All the relevant randomized controlled trials (RCTs) about the acupuncture and moxibustion prevention and treatment of PMOP will be included. Furthermore, we will only include Chinese and English literatures due to the limitation of language ability. We will import all the retrieved documents that may be included into EndNoteX7 and use the functions of the software to delete duplicate articles and manage them. After special training on the inclusion and exclusion standards, the two reviewers will first independently review and screen all retrieved research titles and abstracts to remove irrelevant articles and include qualified literature to facilitate the next screening. If they cannot identify whether the article can be included by the title and abstract, they will read the full text. All the excluded articles must be marked with a reason and reflected in the flowchart of the study selection process. If there exists divergence in the process of screening the article, the third reviewer will decide whether the article is eligible for inclusion.

Information sources: (1)We will mainly search the electronic databases as following: the Cochrane Central Register of Controlled Trials, PubMed, EMBASE, the Web of Science, China National Knowledge Infrastructure (CNKI), Wan-Fang Database, Chinese Scientific Journal Database(VIP database) and Chinese Biomedical Literature Database (CBM). (2)We will try to contact with authors to get some details that their literatures did not express. (3)We will try our best to find relevant trial registers or grey literatures.

Main outcome(s): Bone mineral density (BMD) and total effective rate will be selected as the primary outcomes.

Additional outcome(s): The additional outcomes including: visual analogue scale (VAS)、TCM syndrome score, biochemical indicators (E2, BGP, Ca/Cr, BALP), adverse events.

Quality assessment / Risk of bias analysis: Two reviewers will independently evaluate the risk of bias of included studies according to the Cochrane Collaboration's tool for assessing risk of bias in randomised trials, which mainly consists of 7 items: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of result evaluation, incomplete outcome data, selective reporting and other sources of bias. These studies will be assessed as "low risk of bias", "high risk of bias" or "unclear risk of bias". Additionally, any disagreements will be discussed and decided by the third reviewer.

Strategy of data synthesis: RevMan V.5.3 statistical software will be used to analyze data when conducting a meta-analysis.Dichotomous variables are displayed by relative risk (RR) with 95% confidence intervals (CIs); continuous variables are expressed by mean difference(MD) or standardized mean difference (SMD) with 95% CIs.For significant heterogeneity (I2 >50%) in clinical researches, we are supposed to conduct subgroup analysis or sensitivity analysis.If the requirements for meta-analysis cannot be met, we will just adopt a systematic narrative analysis to illustrate the included studies.

Subgroup analysis: If the data is sufficient, then we will consider to perform subgroup analysis in the following aspects: different treatment methods, the interval time of acupuncture and moxibustion treatment, treatment period of acupuncture and moxibustion, different parts of bone density detection.

Sensibility analysis: Sensitivity analysis is mainly used to analyze the quality of researches to reduce the influence of low-quality or small sample size literatures on the results of meta-analysis. Therefore, we will perform a sensitivity analysis to evaluate the stability and credibility of the literatures if necessary. When there exists a

high degree of heterogeneity, those highly-sensitive articles will be considered to exclude. If the sensitivity analysis have changed the results, we should pay special attention to it and analyze the corresponding reasons actively.

Language: There is an English language summary and language limits will not be imposed on the search.

Country(ies) involved: China.

Keywords: acupuncture, moxibustion, postmenopausal osteoporosis (PMOP), preventive treatment for disease, systematic review, meta-analysis.

Contributions of each author:

Author 1 - Fangyuan XU did preliminary searching.
Email: 949599987@qq.com
Author 2 - Qiqi Yang provided statistical expertise.
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Author 3 - Wei Huang decided the topic and contributed to the development of the selection criteria.
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