INPLASY PROTOCOL

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Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest: **None.**

The Effect of Qigong Wuqinxi for Osteopenia and Primary Osteoporosis: protocol for a systematic review and meta-analysis

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Review question / Objective: **This study is designed to evaluate the effectiveness and safety of Wuqinxi exercise in the prevention and treatment of osteopenia and primary osteoporosis.**
Condition being studied: **Osteoporosis(OP) and related fragility fractures are a significant public health problem which leads to pain, disability, loss function of independence, considerable complications and increased mortality. Exercise training is the only alternative strategy to improve multiple skeletal and fall risk factors simultaneously. Traditional Chinese exercise therapy has become one of the most popular forms of exercise, but its effectiveness and safety for osteopenia and osteoporosis are not very clear, therefore a further systematic review and meta-analysis are necessary. The potential outcomes we mainly focused on will inckude BMD, bone turnover markers, osteoporosis-related fractures, quality of life, pain scores, and adverse events.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 April 2020 and was last updated on 22 April 2020 (registration number INPLASY202040135).

INTRODUCTION

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Rationale: Wuqinxi is one of the Chinese mind-body exercises using to improve physical and mental health and fight against diseases for thousands of years. Our study aims to systematically review the existing literature to further explore the efficacy and safety of Wuqinxi in the prevention and treatment of osteopenia and osteoporosis.

METHODS

Search strategy: Two researchers (ML & DYL) will independently perform the literature search in the form of "back-to-back". A combination of medical subject headings(Mesh) and text words will be used to develop the literature search strategies, mainly including①Wuqinxi, Five-Animal Exercise, five mimic-animal exercises, five-animal boxing or Qigong;②osteopenia, osteoporosis, postmenopausal osteoporosis, primary osteoporosis, senile osteoporosis, bone mineral density, bone loss, low bone mass, bone*turnover*markers; ③clinical trial or randomized controlled trial. PubMed, Science Citation Index, Embase(Ovid) database, the Cochrane Library, and 4 Chinese databases(the China National Knowledge Infrastructure, the China Biology Medicine disc, the China Science and Technology Journal Database, and the Wan fang Database) will be searched from database inception to 1 June 2020. ClinicalTrials.gov and the Chinese Clinical Trial Registry Platform will be searched for ongoing or recently completed trials. Besides, we will scan the reference lists of included studies or relevant reviews to identify additional eligible studies, while the papers and unpublished reports will be hand-searched to ensure more complete coverage of the topic.

Participant or population: We will include studies on people who are osteopenia and primary osteoporosis(POP) or a population at high risk of osteoporosis(50 years or older). The clinical diagnosis of osteopenia and POP should be in accordance with internationally recognized criteria. For instance, the World Health Organization criteria: BMD of subjects evaluated by dual-energy X-ray absorptiometry (DXA) could be categorized as: normal (T-score ＞-1); osteopenia, namely low bone mass (T-score in the range of -2.5 and -1); osteoporosis (T-score＜or =-2.5).

Intervention: A comparison of Wuqinxi monotherapy against other treatments will be included, Wuqinxi plus another intervention versus the same intervention alone (e. g, Wuqinxi and Calcium versus only Calcium) will be also enrolled. Any type of Wuqinxi will be included regardless of exercise version, frequency, and duration.

Comparator: The control group can receive a placebo, no treatment, vitamin D tablets, exercise or guideline-recommended conventional treatment. If the control group contains other non-conventional therapies, such as TaiChi, physiotherapy, herbal medicine, acupuncture, moxibustion, massage, yoga, it will be excluded.

Study designs to be included: Only randomized controlled trials (RCTs) including combination therapy and monotherapy of Wuqinxi will be included.

Eligibility criteria: Only randomized controlled trials will be enrolled, in which the intervention group must include a form of Wuqinxi, while the control group can involve other conventional treatment or no intervention. The potential outcome measures will include BMD values, bone turnover markers, fragility fractures, quality of life, pain scores, and adverse events.

Information sources: PubMed, Science Citation Index, Embase(Ovid) database, the Cochrane Library, and 4 Chinese databases(the China National Knowledge Infrastructure, the China Biology Medicine disc, the China Science and Technology Journal Database, and the Wan fang Database) will be searched from database inception to 1 June 2020. ClinicalTrials.gov and the Chinese Clinical Trial Registry Platform will be searched for ongoing or recently completed trials. Besides, we will scan the reference lists of included studies or relevant reviews to identify additional eligible studies, while the papers and unpublished reports will be hand-searched to ensure more complete coverage of the topic. Two researchers (ML & DYL) will independently perform the literature search in the form of "back-to-back", and we will contact the author for more details of the study to solve questions about eligibility if necessary.

Main outcome(s): 1) Changes in BMD values; 2) Bone turnover markers (BTMs), such as procollagen type 1 N-peptide(P1NP) and serum C-terminal telopeptide of type 1 collagen(S-CTX); 3) Osteoporosis-related fractures (fragility fractures).

Additional outcome(s): 1) Quality of life as measured by validated scales, such as the Short Form (SF)-36; 2) A recognized pain scores including the Visual Analog Scale for Pain (VAS Pain); 3) Any adverse events related to Wuqinxi for treatment or prevention during the trial.

Data management: Data extraction for eligible studies will be performed independently by 2 reviewers (ML & DYL) using a pre-designed standardized form. We will provide guidance and interpretation for the contents of the extraction form before data extraction. The detailed data extraction form will mainly consist of basic information, population characteristics, methodological description, intervention characteristics, outcome data, conclusion and follow-up assessment. We will contact the original researchers for missing data. The third reviewer (PPH) will be responsible for checking the data extracted by the two reviewers. Inconsistencies will be resolved by discussion, and consulting the superior expert (QC) to facilitate the decision when a disagreement persisting.

Quality assessment / Risk of bias analysis: The methodological quality of individual studies will be judged following the criteria from the Cochrane Handbook for Systematic Reviews of Interventions Version 5.3.0. The judgments of all included studies will be made independently by two reviewers (ML & DYL), and we will conduct training of reviewers and calibration exercises before the start of the review to ensure consistency between reviewers. There are seven domains, each of which will be rated as "yes"(indicating a low risk of bias), "no"(indicating a high risk of bias), or "unclear"(indicating either an uncertainty for bias or lack of information). The original study investigators will be contacted if any uncertainty exists. We plan to compute graphic representations of potential bias within and across studies using Review Manager 5.3. Those with inconsistent opinions will be resolved through negotiation or consult the superior expert (QC) to reach a consensus.

Strategy of data synthesis: We will perform a systematic narrative synthesis to summarize and explain the characteristics and findings of the included studies and provide this information in the text and tables. Review Manager 5.3 provided by the Cochrane Collaboration will be used for the meta-analysis (If feasible), and the random-effects model will be chosen to combine all summary outcome measures. If a meta-analysis is impossible, the results of clinical trial comparisons will be analyzed descriptively. Dichotomous outcomes (e.g., effective and ineffective) will be determined by relative risk (RR) with 95% confidence interval (CI), while continuous data will be analyzed using weighted mean difference (if measurement methods are consistent) or standardized mean difference (if measurement methods are different). When there are missing data, we will contact the

study authors via email to obtain detailed accurate data. If the missing data are not available finally, we will carefully estimate the important numerical data, for example using an interpolation method. Moreover, the potential impact of missing data on the overall results of the study will be assessed using sensitivity analysis. It is possible to include multi-arm trials, we will combine the relevant groups into a single group according to the formula provided in the Cochrane handbook 5.3.0.

Subgroup analysis: Subgroup analysis will be further stratified by type of subjects (elderly, postmenopausal women), diagnosis (osteoporosis, low bone mass), BMD at different skeletal regions (lumbar spine, femoral or total hip), treatment type, or co-interventions.

Sensibility analysis: To explore the robustness of our meta-analysis, we will compare the results before and after by removing one study each time and then pooling the remaining studies. When the heterogeneity test suggests I2＜50% or P＞0.1, we will compare whether the results are consistent after replacing the random-effects model with a fixed-effect model in the meta-analysis.

Language: Only studies reported in English or Chinese language will be included due to resource limits.

Country(ies) involved: China.

Keywords: Wuqinxi; osteoporosis; bone mineral density; protocol; systematic review.

Dissemination plans: The results of the study will be published in peer-reviewed publications and disseminated electronically or in print.

Contributions of each author:
Author 1 - Min Liu designed the study protocol and drafted the manuscript.
Author 2 - Dongying Liu wrote and refined the manuscript.
Author 3 - Peipei Hong is resposible for data curation and investigation.
Author 4 - Xianliang Qiu checked the manuscript.
Author 5 - Qiu Chen revised and finalized the study protocol.