INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Comparing the effectiveness and safety of different Chinese traditional exercise modalities, frequency and duration in osteoporosis: a protocol for systematic evaluation and network meta-analysis of randomized controlled trials

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Review question / Objective: Comparing the effectiveness and safety of different Chinese traditional exercise modalities, frequency and duration in osteoporosis.

Information sources: We will conduct literature searches in the Cochrane Library, Web of Science, PubMed, Embase, China Biomedical Literature Database, China Knowledge Network, China Science and Technology Journal Database, and Wanfang Database. The time period is from the inception of the database to January 2022. The language of the article should be English or Chinese. Search terms used include: qigong or taiji or taijiquan or baduanjin or traditional Chinese exercise or osteoporosis or bone loss, etc. The type of article was limited to a randomized controlled study.

INTRODUCTION

Review question / Objective: Comparing the effectiveness and safety of different Chinese traditional exercise modalities, frequency and duration in osteoporosis.

Condition being studied: This systematic evaluation will summarize the current evidence on traditional Chinese exercise for osteoporosis, determine its effects on osteoporotic fractures, bone mineral

density, and pain, and provide a complement to non-pharmacological treatments for osteoporosis. We plan to use a network meta-analysis to compare the efficacy and safety of different traditional exercise modalities for intervention in osteoporosis, to explore the best Chinese traditional exercise modalities and their ranking, and to provide evidence for developing a treatment plan for the best Chinese traditional exercise modalities, frequency and duration of exercise for patients with osteoporosis, and to provide a convenient and cost-effective way to prevent and treat osteoporosis in middle-aged and older adults. Translated with http://www.DeepL.com/Translator (free version).

METHODS

Participant or population: Patients diagnosed with primary osteoporosis will be included. (Diagnostic criteria: Based on dual-energy X-ray (DXA) measurements: BMD values of 1 standard deviation or less than the peak bone mass of healthy adults of the same sex and race are considered normal; below 1.0 to 2.5 standard deviations are considered low bone mass (or low bone mass); below ≥2.5 standard deviations are considered osteoporosis.

Intervention: The intervention in the control group consisted of conventional medication such as calcium, vitamin D, anti-bone resorption drugs, and bone synthesis drugs. The experimental group was treated with Traditional Chinese Exercise (such as Taijiquan, Qigong, Baduanjin) alone or combined with exercise on the basis of routine intervention measures in the control group. (Two authors will make judgments about the inclusion of uncertain exercise modalities.)

Comparator: The intervention in the control group consisted of conventional medication such as calcium, vitamin D, anti-bone resorption drugs, and bone synthesis drugs.

Study designs to be included: Clinical randomized controlled trials (RCTs).

Eligibility criteria: Participants: Patients diagnosed with primary osteoporosis will be included. (Diagnostic criteria: Based on dual-energy X-ray (DXA) measurements: BMD values of 1 standard deviation or less than the peak bone mass of healthy adults of the same sex and race are considered normal; below 1.0 to 2.5 standard deviations are considered low bone mass (or low bone mass); below ≥2.5 standard deviations are considered osteoporosis. (36))Intervention: The intervention in the control group consisted of conventional medication such as calcium, vitamin D, anti-bone resorption drugs, and bone synthesis drugs. The experimental group was treated with Traditional Chinese Exercise (such as Taijiquan, Qigong, Baduanjin) alone or combined with exercise on the basis of routine intervention measures in the control group. (Two authors will make judgments about the inclusion of uncertain exercise modalities.)Outcomes: Primary outcome: BMD. Secondary outcomes: Bone conversion markers, fracture incidence, adverse events, pain scores (visual analog scale, VAS), quality of life scores, and functional scores.Study design: Clinical randomized controlled trials (RCTs).

Information sources: We will conduct literature searches in the Cochrane Library, Web of Science, PubMed, Embase, China Biomedical Literature Database, China Knowledge Network, China Science and Technology Journal Database, and Wanfang Database. The time period is from the inception of the database to January 2022. The language of the article should be English or Chinese. Search terms used include: qigong or taiji or taijiquan or baduanjin or traditional Chinese exercise or osteoporosis or bone loss, etc. The type of article was limited to a randomized controlled study.

Main outcome(s): Primary outcome: BMD. Secondary outcomes: Bone conversion markers, fracture incidence, adverse events, pain scores (visual analog scale,

VAS), quality of life scores, and functional scores.

Quality assessment / Risk of bias analysis: All included studies will be assessed for risk of bias using the Cochrane Collaboration's Risk of Bias tool. It includes the following main areas: (1) sequence generation and allocation concealment (2) blinding of participants and personnel (3) blinding of outcome data (4) incomplete outcome data (5) selective outcome reporting (6) funding source. The risk of bias for each domain will be categorized as low, unclear, or high. We will use Revman (V.5.4) software to do the risk of bias assessment chart. We will use the Grading of Recommended Assessment, Development and Evaluation Guideline Development Tool (GRADE) to assess the quality of the evidence and to specify the recommended level of evidence. In addition, we will use CINeMA (a new method to assess the confidence level of network meta-analysis results) to assess the credibility of the results of this network meta-analysis.

Strategy of data synthesis: Among all statistical results $p<0.05$ was considered statistically significant. If the outcome indicator is a dichotomous variable, odds ratios (OR) with 95% confidence interval (CI) will be used as the effect size. If the outcome indicator is a continuous variable, the mean difference (MD) or standardized mean difference (SMD) with 95% confidence interval (CI) will be used as the effect size. Pairwise meta-analyses: If there are more than 2 studies on the same pair of interventions, we will use Revman (V.5.4) software for pairwise meta-analysis. Heterogeneity among trials was identified by the $\chi2$ test and reported as I2. If I2 50%, heterogeneity is indicated and a random effects model will be used. We will use the contribution matrix to show the impact of each pairwise meta-analysis on the results. Network meta-analysis (NMA): We will use Stata (V.16.0) software to plot a network for each outcome, where each node represents an intervention and the line between nodes represents a direct comparison between the two, with the size of the nodes and lines proportional to the number of included studies. We will use GeMTC (V.0.14.3) software and Markov chain Monte Carlo to perform Bayesian network meta-analysis to compare multiple interventions simultaneously. We intend to set the initial parameters of GeMTC as follows: 4 simulation chains, 10 steps (refinement interval), 50 000 iterations and the first 20 000 for annealing to eliminate the influence of the initial values. We will use the Brooks-Gelman-Rubin statistical method to evaluate Evaluating convergence. Convergence among the included studies will be expressed as Potential Scale Reduced Factor (PSRF), which indicates good convergence when the PSRF is close to or equal to 1. The split node method will be used for each loop in the network meta-analysis to compare the agreement between direct and indirect evidence. If P > 0.05, it indicates a consistency. Probability ranking charts can help us assess the efficacy of various interventions. We will use the surface size under the cumulative ranking curve (SUCRA) to obtain the ranking of all interventions.

Subgroup analysis: Two subgroup analyses will be performed to determine the effect of exercise frequency and duration on outcomes. Based on previous experience, the study duration will be divided into three subgroups, <12 months vs. 12-18 months vs. 4 times/week as high frequency and ≤4 times/week as low frequency. Then we will perform a subgroup analysis to explore the most appropriate frequency of exercise. If there are enough studies, we will also perform a subgroup analysis of the participants' age and sex ratios, severity of OP at baseline, pain level, and frequency of exercise.

Sensitivity analysis: We will perform sensitivity analyses, including excluding RCTs with low methodological quality or removing incomplete data.

Language: English.

Country(ies) involved: China.

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