

INPLASY PROTOCOL

To cite: Ying et al. Network meta analysis of four kinds of traditional Chinese fitness methods in the treatment of osteoporosis in the elderly. Inplasy protocol 202040114. doi: 10.37766/inplasy2020.4.0114

Received: 19 April 2020

Published: 19 April 2020

Corresponding author:
Hailiang Huang

06000031@sducm.edu.cn

Author Affiliation:
Shandong University of TCM

Support: School Project

Review Stage at time of this submission: Formal screening of search results against eligibility criteria.

Conflicts of interest:
None.

Network meta analysis of four kinds of traditional Chinese fitness methods in the treatment of osteoporosis in the elderly

Ying, Y¹; Gong, Z²; Tao, H³; Hailiang H⁴.

Review question / Objective: Randomized controlled trial. The subjects of this study are elderly osteoporosis patients, whose gender and race are not limited. The intervention measures were consistent with the baseline treatment. The experimental group was treated with Chinese traditional fitness skills (Baduanjin or Taijiquan or Wuqinxi or Yijinjing) combined with western medicine, while the control group was treated with western medicine. Outcome indicators: 1. Clinical efficiency; 2. Total BMD score; 3. Lumbar L2-4BMD score; 4. Femoral neck BMD score; 5. Ward's triangle BMD score; 6. VAS scale; 7. BGP index; 8. Serum index comparison (including ALP, blood calcium, blood phosphorus, β - CTX), etc. Four kinds of traditional Chinese fitness skills are clinically comparable, but their actual clinical efficacy is lack of evidence-based basis. Therefore, this study uses the network meta-analysis method to summarize and conduct quantitative statistical analysis on four kinds of different traditional Chinese fitness skills, and then selects the best clinical treatment fitness skills, in order to provide reliable evidence-based medical evidence for clinical practice.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 April 2020 and was last updated on 19 April 2020 (registration number INPLASY202040114).

INTRODUCTION

Review question / Objective: Randomized controlled trial. The subjects of this study are elderly osteoporosis patients, whose gender and race are not limited. The intervention measures were consistent with the baseline treatment. The experimental group was treated with Chinese traditional

fitness skills (Baduanjin or Taijiquan or Wuqinxi or Yijinjing) combined with western medicine, while the control group was treated with western medicine. Outcome indicators: 1. Clinical efficiency; 2. Total BMD score; 3. Lumbar L2-4BMD score; 4. Femoral neck BMD score; 5. Ward's triangle BMD score; 6. VAS scale; 7. BGP index; 8. Serum index comparison

(including ALP, blood calcium, blood phosphorus, β - CTX), etc. Four kinds of traditional Chinese fitness skills are clinically comparable, but their actual clinical efficacy is lack of evidence-based basis. Therefore, this study uses the network meta-analysis method to summarize and conduct quantitative statistical analysis on four kinds of different traditional Chinese fitness skills, and then selects the best clinical treatment fitness skills, in order to provide reliable evidence-based medical evidence for clinical practice.

Rationale: Many clinical practices have proved that different Chinese traditional fitness methods not only have a positive influence on the physical quality, mental health, physiological function, but also can effectively improve the muscle strength of the elderly and enhance the balance ability. This study is to use the network meta-analysis method, make a comprehensive statistical analysis and ranking of four fitness of the same evidence body for the treatment of this disease.

Condition being studied: Osteoporosis is a kind of metabolic osteopathy characterized by the decrease of bone mass and the destruction of bone microstructure, which leads to the increase of bone fragility and fracture. As a more difficult disease in clinical treatment, the disease not only seriously affects the daily work and quality of life of patients, but also brings greater psychological pressure to patients, so it is particularly important to select the best intervention measures. In recent years, Chinese traditional fitness methods have played an important role in the treatment of the disease. Many clinical practices have proved that different Chinese traditional fitness methods not only have a positive influence on the physical quality, physical form, mental health, physiological function and other aspects of the elderly, but also can effectively improve the muscle strength of the elderly and enhance the balance ability of the patients. However, there is no scientific evidence for evidence-based evaluation. Therefore, the purpose of this

study is to use the network meta-analysis method, make a quantitative comprehensive statistical analysis and ranking of four methods of the same evidence body for the treatment of this disease, so as to provide reliable evidence-based basis for clinicians.

METHODS

Search strategy: By using the computer retrieval technology, the clinical randomized controlled trials of four kinds of fitness and exercise methods of traditional Chinese medicine for osteoporosis patients were carried out, and the self built database was set up until January 31, 2020. Computer retrieval includes CNKI (Chinese Journal Full-text Database), CBM (Chinese biomedical literature database), Wanfang Data (Wanfang science and technology information database), VIP (China Weipu scientific and technological journal database) and other Chinese databases. The Cochrane Library, PubMed, Embase, Web of Science and other foreign databases were also searched. Chinese search words include fitness Qigong, traditional skills, Baduanjin, Taijiquan, Wuqinxi, Yijinjing, osteoporosis, random control, etc. different databases choose the corresponding combination of subject words, free words and key words. The English search terms are Health Qigong, fitness skill, Baduanjin, Taijiquan, Wuqinxi, Yijinjing, osteoprosis, randomized controlled trials.

Participant or population: The type of study was clinical randomized controlled trial (RCT). The subjects of the study were patients who were definitely diagnosed with osteoporosis, and there were no restrictions on the sex and race of these patients. The original literature should have a clear diagnosis standard of Western medicine or traditional Chinese medicine. It should conform to the relevant standards of the diagnosis and treatment guide for primary osteoporosis issued by the osteoporosis and bone mineral Disease Branch of the Chinese Medical Association, or the QCT diagnosis standard for

osteoporosis of lumbar spine issued by the American College of Radiology (ACR), or according to the expert consensus on the diagnostic criteria of Chinese osteoporosis prepared by the osteoporosis and bone mineral Disease Branch of Chinese Medical Association and the diagnostic criteria of osteoporosis issued by the World Health Organization (WHO).

Intervention: In the case of clear diagnosis standard, curative effect judgment standard and consistent basic treatment, the experimental group was treated with single exercise method (Baduanjin or Taijiquan or Wuqinxi or Yijinjing), while the control group was treated with no exercise intervention (blank control).

Comparator: The control group was treated with no exercise intervention.

Study designs to be included: The type of study was clinical randomized controlled trial (RCT), and there were no restrictions on the sex and race of these patients.

Eligibility criteria: The original literature should have a clear diagnosis standard of Western medicine or traditional Chinese medicine. It should conform to the relevant standards of the diagnosis and treatment guide for primary osteoporosis issued by the osteoporosis and bone mineral Disease Branch of the Chinese Medical Association, or the QCT diagnosis standard for osteoporosis of lumbar spine issued by the American College of Radiology (ACR), or according to the expert consensus on the diagnostic criteria of Chinese osteoporosis prepared by the osteoporosis and bone mineral Disease Branch of Chinese Medical Association and the diagnostic criteria of osteoporosis issued by the WHO.

Information sources: By using the computer retrieval technology, the clinical randomized controlled trials of four kinds of fitness and exercise methods of traditional Chinese medicine for osteoporosis patients were carried out, and the self built database was set up until January 31, 2020. Computer retrieval includes CNKI (Chinese Journal Full-text

Database), CBM (Chinese biomedical literature database), Wanfang Data (Wanfang science and technology information database), VIP (China Weipu scientific and technological journal database) and other Chinese databases. The Cochrane Library, PubMed, Embase, Web of Science and other foreign databases were also searched. When searching the literature, the subject words and free words shall be searched separately, and the relevant free words and terms shall be used for comprehensive search. Meanwhile, the research of WHO international clinical trial registration platform and [ClinicalTrials.gov](https://www.clinicaltrials.gov) shall be searched to determine the additional potential trial registration. In addition, the relevant journals shall be searched in the reference literature, and the relevant literature shall be tracked, and Google scholars shall be used together Baidu academic and other relevant search engines conduct relevant research on the Internet by hand, and will provide data for all relevant authors and major researchers to supplement the incomplete report or unpublished research of the original paper. We will try our best to ensure that the primary search work is comprehensive so as not to lose valuable research materials. At the same time, according to the PICOS search principle, we will include the research that meets the standards and organize and create the database.

Main outcome(s): Outcome indicators: 1. Clinical efficiency; 2. Total BMD score; 3. Lumbar L2-4BMD score; 4. Femoral neck BMD score; 5. Ward's triangle BMD score; 6. VAS scale; 7. BGP index; 8. Serum index comparison (including ALP, blood calcium, blood phosphorus, β - CTX).

Additional outcome(s): Not applicable.

Data management: The type of study was clinical randomized controlled trial (RCT). The subjects of the study were patients who were definitely diagnosed with osteoporosis, and there were no restrictions on the sex and race of these patients. The original literature should have a clear diagnosis standard of Western

medicine or traditional Chinese medicine. The intervention measures were consistent with the baseline treatment. The experimental group was treated with Chinese traditional fitness skills (Baduanjin or Taijiquan or Wuqinxi or Yijinjing) combined with western medicine, while the control group was treated with western medicine. First, EndnoteX9 software is used to search the repeated questions, merge the literature retrieval results in different databases, establish the information database and download the full text. Then, the data were extracted by two researchers independently, cross checked and reviewed according to the pre-determined tables. The content of data extraction includes: (1) Basic information (including the first author, published journal and year, research topic of the literature); (2) Relevant information of the experimental group and the control group in the literature (including case number, total case number, gender, age, intervention measures, treatment course); (3) Design type and quality evaluation information of the literature; (4) Outcome indicators: 1. Clinical efficiency; 2. Total BMD score; 3. Lumbar L2-4BMD score; 4. Femoral neck BMD score; 5. Ward's triangle BMD score; 6. VAS scale; 7. BGP index; 8. Serum index comparison (including ALP, blood calcium, blood phosphorus, β - CTX), etc. According to Cochrane 5.1 manual standard, Revman 5.1 statistical software was used for literature quality evaluation and bias risk evaluation, and R language programming software was used for data integration and network meta-analysis.

Quality assessment / Risk of bias analysis:

According to Cochrane evaluator system recommended by the manual version 5.1 quality evaluation tools, evaluate the methodological quality included in the study by random method, allocation concealment and blinding, ending data integrity, selective reports, fall off the number of cases, follow-up and other bias, and each project is divided into high risk, low risk and uncertainty risk three options, according to the included in the description

of the research on the above aspects, the identification and quality evaluation.

Strategy of data synthesis: First, we will perform a traditional pairwise meta-analysis to integrate all the direct evidence. Second, we will use NMA to synthesize direct and indirect evidence. Bayesian framework and Markov chain Monte Carlo (MCMC) sampling techniques based on R software will be used to generate summary mean differences and summarize OR. The tracking graph and density graph will be used to evaluate the convergence of the simulation. Secondly, statistics based on Bayesian meta-analysis will be used to render NET diagram, contribution diagram, inconsistency test diagram, comparative adjustment funnel diagram, forest diagram and other relevant drawings using ADDIS software. This network meta-analysis will follow PRISMA statements.

Subgroup analysis: R software and ADDIS1.16.6 statistical software was used to analyze the treatment measures, and Network relationship diagram and sparse sequence diagram of various interventions were drawn at the same time. Call the software through the related instructions based on bay leaf, MCMC (Markov chain Monte Carlo) algorithm for data results of random effects model for prior assessment and treatment (using four chain simulation analysis, the initial value of 2.5, elaboration iteration step 10, 20000 to adjust the number of iterations, analog iterative times, 50000 times), with $P < 0.05$ and 95% confidence interval (CI) as a standard for statistically, count data by OR value (odds ratio) for curative effect analysis of statistics; Measurement data were represented by weighted Mean Difference or standardized Mean Difference (MD), and all effect sizes were represented by 95%CI Confidence Intervals (95%CI). The node-split Model was used to conduct the inconsistency test. When there was no statistical difference among the subgroups ($P > 0.05$), it showed that the heterogeneity of the included studies was small, so the Consistency Model was used for analysis. Conversely the non consistency Model (Inconsistency Model) for analysis. The

PSRF (Potential Scale reduction Factor) reflects the convergence. When the PSRF is both close to 1 or equal to 1, it indicates that the convergence efficiency has been achieved, and the results obtained from the consistency model analysis have a high credibility.

Sensibility analysis: If the result of meta-analysis is positive and there are more than 3 included studies, R software shall be used to conduct sensitivity analysis on the statistical results, and meta-analysis shall be carried out again for each excluded study, and the results shall be compared with those before exclusion. If there is no substantial change in the comparative analysis, the results are stable. Otherwise, the data results are not stable. If significant heterogeneity is found, subgroup analysis will be envisaged based on treatment time, age, race, gender and quality of study to investigate possible sources of heterogeneity.

Language: English.

Country(ies) involved: China.

Keywords: Fitness skill, Baduanjin, Taijiquan, Wuqinxi, Yijinjing, Osteoporosis, Network meta-analysis.

Contributions of each author:

Author 1 - Author 1 is Ying Yu, who is drafted the conceptualization, data curation, formal analysis, methodology, software, writing-original draft, writing-review&editing of the manuscript. Also contributed to the development of the selection criteria and the risk of bias assessment strategy.

Author 2 - Author 2 is Gong Zhang, who is drafted the conceptualization, data curation, formal analysis, methodology, software, writing-original draft, writing-review&editing of the manuscript. Also contributed to the development of the selection criteria and the risk of bias assessment strategy.

Author 3 - Author 3 is Tao Han, who is drafted the project administration, supervision and revised the manuscript. As

a major funder, it also provides important financial support.

Author 4 - Author 4 is Hailiang Huang, who is drafted the project administration, supervision and revised the manuscript. Also provided important supports during design of the study and collection, analysis, and interpretation of data and in writing the manuscript.