INPLASY PROTOCOL

Corresponding author:
Jieying Li

lijieying59@163.com

Author Affiliation:
Henan University of Chinese Medicine

Support: None.

Review Stage at time of this submission: Preliminary searches.

Conflicts of interest: None.

Baduanjin exercise for patients with knee osteoarthritis: a protocol for systematic review and meta-analysis

Li, JY[4]; Yin, S[2]; Li, RQ[3]; Su, KQ[4]; Zhang, ZH[5]; Feng, XD[6]; Wu, N[7].

Review question / Objective: Can Baduanjin exercise benefit for treating knee osteoarthritis?

Condition being studied: Knee osteoarthritis (KOA) is a common chronic degenerative disorder and the leading cause of pain in the elderly. KOA is characterized by progressive loss of articular cartilage, subchondral bone thickening, bone hypertrophy, and new bone formation. Pain symptoms and physical function disability are the primary clinical symptoms of KOA. In addition, with disease progression, KOA may impair patients'normal quality of life. Baduanjin is a traditional chinese mind-body exercise routine.Some Data came from papers and researches reveal that Baduanjin exercises produce a great effect on improving the pain, stiffness and mobility of KOA patients. while some other reports indicate that there are no significant differences for effects of KOA by practicing Baduanjin. Therefore, This study will summarizes and evaluates the effect of existing clinical trials on the KOA by Baduanjin.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 September 2020 and was last updated on 12 September 2020 (registration number INPLASY202090051).

INTRODUCTION

Review question / Objective: Can Baduanjin exercise benefit for treating knee osteoarthritis?

Condition being studied: Knee osteoarthritis (KOA) is a common chronic degenerative disorder and the leading cause of pain in the elderly. KOA is characterized by progressive loss of articular cartilage, subchondral bone thickening, bone hypertrophy, and new bone formation. Pain symptoms and physical function disability are the primary clinical symptoms of KOA. In addition, with disease progression, KOA may impair patients'normal quality of life. Baduanjin is

a traditional chinese mind-body exercise routine.Some Data came from papers and researches reveal that Baduanjin exercises produce a great effect on improving the pain, stiffness and mobility of KOA patients. while some other reports indicate that there are no significant differences for effects of KOA by practicing Baduanjin. Therefore, This study will summarizes and evaluates the effect of existing clinical trials on the KOA by Baduanjin.

METHODS

Search strategy: The search terms are: ('Osteoarthritides'OR'Osteoarthrosis'OR 'Osteoarthroses'OR'Arthritis, Degenerative'OR'Arthritides, Degenerative' OR'Degenerative Arthritides' OR 'Degenerative Arthritis' OR 'Arthrosis' OR 'Arthroses'OR'Osteoarthrosis Deformans') AND ('Baduanjin' OR'eight section brocades' OR'eight-section Brocade' OR 'eight section brocades' OR 'eight trigrams boxing' OR 'eight-treasured exercises' OR 'eight pieces of brocade'OR 'Eight Brocade Section' Baduanjin exercises'OR 'Baduanjin exercise' OR 'Baduanjin Qigong'). Chinese translations of these terms will be applied to Chinese database. Initially, and to increase the chance of identifying all relevant papers, the search will not be limited to any specific criteria. Articles published in English and Chinese will be considered. The reference list of the identified papers will also be searched. The identified articles will be imported into the EndNote reference management software. This software will help to identify any duplicates. The titles and abstracts will be screened. We will retrieve the full text of the relevant papers for further assessment.

Participant or population: Patients diagnosed with KOA.

Intervention: Studies were included if Baduanjin exercise was used as the sole intervention.

Comparator: A waiting list, placebo, no intervention, educational classes, healthcare routine, or other behavioral as controls was included.And we excluded studies in which other Exercise Therapy and other traditional Chinese medicine (TCM) therapies (e.g. moxibustion, Chinese Tuina, acupuncture, Chinese herbals) and Western medicine therapy.

Study designs to be included: The type of study was clinical randomized controlled trial (RCT).

Eligibility criteria: Eligibility criteria were detailed using the Participants, Interventions, Controls, Outcomes, and Studies (PICOS) framework.

Information sources: We will perform medical retrieval in the following database: PubMed, EMBASE, Cochrane Library, Web of Science, National Knowledge Infrastructure (CNKI), Wanfang Data Information Site, Chinese BioMedical Database(CBM), Chinese Science and Technique Journals Database (VIP).

Main outcome(s): The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) used to assess pain,stiffness and physical functioning.

Additional outcome(s): The Visual Analogue Scale (VAS); Knee Injury and Osteoarthritis Outcome Score (KOOS); the Medical Outcomes Study Short Form-36 (SF-36); six-minute walk test (6-MWT); active range of motion (AROM); Berg Balance Scale (BBS); the Isokinetic Strength of the Knee Extensors (ISKE); Lequesne &Mery Index.

Data management: Two reviewers will independently assess the eligibility of the studies retrieved against the inclusion and exclusion criteria. Then those studies meeting the criteria will be selected for use in the review.The following data will then be extacted from the studies selected for inclusion using a data collection form,and recorded in an Excel file:(1) Details of study: first author, year of publication;(2) Study population: age, sex, sample size;(3)

Intervention characteristics: type, frequency and duration;(4) Outcome measures: Clinical effective rate, WOMAC, VAS, The KOOS ,adverse effects and so on.

Quality assessment / Risk of bias analysis:
The methodological quality of included studies will be evaluated in terms of concealment allocation, randomisation, blinding and other biases, by two authors according to the Cochrane revised tool for risk of bias. Particular attention will be paid to the adequacy of the random allocation concealment and blinding measures used, due to the potential for failure in studies in which these have been inadequately handled. IN addition, the sample size calculation method, the reporting of withdrawals and follow-ups, and other sources of bias will also be assessed, and another two authors (Xiaojiang Yu and Wei Wu) will assess the quality of the evidence using the GRADE framework, covering study limitations, inconsistencies, indirectness, imprecision and publication biases.

Strategy of data synthesis:
We will perform the Cochrane's Review Manager software (V.5.3) to analyse statistics. It is used 95% confidence intervals (CIs) to the mean difference (MD) or standardized mean difference (SMD) to analyze continuous outcomes. About the assess to heterogeneity and to choose the effect model will take I^2 statistic and χ^2-test adopting. When I^2 statistic >50% and P-value less than 0.1 that we consider heterogeneity exists in research at the same time a random-effects model was selected. On the contrary, the selection of a fixed-effects model.

Subgroup analysis:
Subgroup analysis will be carried out if significant levels of heterogeneity, or any incongruities, are detected within the analysis.

Sensibility analysis:
Sensitivity analysis may be performed by removing low quality studies, or trials with a short-term follow-up.

Language:
We will include reports of randomized controlled trials (RCTS) conducted in English or Chinese.

Country(ies) involved:
China.

Keywords:
Baduanjin exercise, knee osteoarthritis, systematic review, meta-analysis.

Contributions of each author:
Author 1 - Jieying Li.
Author 2 - Shuai Yin.
Author 3 - Ruiqing Li.
Author 4 - Kaiqi Su.
Author 5 - Zhenhua Zhang.
Author 6 - Xiaodong Feng.
Author 7 - Nan Wu.