INPLASY PROTOCOL

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None declared.

The Tai Chi trainning for female patients with knee osteoarthritis: A protocol for systematic review and meta analysis

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Review question / Objective: **This systematic review is aim to objectively evaluate whether Tai Chi training is a more effective and safer therapy for women suffering KOA.**
Condition being studied: **Knee osteoarthritis (KOA) is a chronic degenerative bone and joint disease characterized by joint pain, swelling, ankylosis and functional disorders. Tai chi is a traditional Chinese mind-body practice, which is strongly recommended for patients with KOA by clinical guidelines. Previous systematic reviews mostly focused on demonstrating that Tai Chi could relieve pain and improve physical function in the patients with KOA. However, there is no Tai Chi training systematic reviews that specifically targeted a female population with KOA.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 June 2021 and was last updated on 19 June 2021 (registration number INPLASY202160062).

INTRODUCTION

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METHODS

Search strategy: The following databases will be searched from the establishment database to 2021 to May 31: (1) English database: Pedmed, Cochrane Library, EMBASE, MEDLINE (2) Chinese database: CNKI, Wanfang, CQVIP. There is no language restrictions. The key search terms are [("Knee Osteoarthritis"OR"Knee Osteoarthritides"OR"Osteoarthritis of Knee"OR"Osteoarthritis of the Knee")AND("Tai ji"OR"Tai-ji"OR"Tai Chi "OR"Chi, Tai"OR"Tai Ji Quan"OR"Ji Quan, Tai"OR"Quan, Tai Ji"OR"Taiji"OR "Taijiquan"OR"T'ai Chi"OR"Tai Chi Chua")]. Besides, we will manually retrieve relevant conference papers, medical journal lists and search for new Trials related to this topic in ClinicalTrials.gov and the WHO International Clinical Trials Registry (ICTRP).

Participant or population: Women with knee osteoarthritis and a clear diagnostic criteria.

Intervention: The intervention method of the experimental group is Tai Chi training, which has no restriction on types or training periods.

Comparator: The intervention method of the control group should be one of the following treatment methods: self-help program, other exercise, physical therapy, placebo, or no treatment.

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

Eligibility criteria: Firstly, the randomized controlled trials (RCTs) are eligible, whether or not the blind method is specifically described. There are no restrictions on languages.Secondly, if the full article cannot be obtained, the article will be excluded. Thirdly, systemic evaluation and review literature will be excluded. Last but not the least, the article repeatedly published will be deleted.

Information sources: The following databases will be searched from the establishment database to 2021 to May 31: (1) English database: Pudmed, Cochrane Library, EMBASE, MEDLINE (2) Chinese database: CNKI, Wangfang, CQVIP. Besides, we will manually retrieve relevant conference papers, medical journal lists and search for new Trials related to this topic in ClinicalTrials.gov and the WHO International Clinical Trials Registry (ICTRP).

Main outcome(s): Total score of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and Clinical efficacy will be regarded as the primary outcomes.

Additional outcome(s): Physical performance tests include the measures of the gait kinematics or kinetics changes, the Short Physical Performance Battery(SPPB), the Irrgang knee joint motor function scales and the changes of Balance ability, walking speed, muscle strength, body mass index(BMI). Psychological performance tests include the Pittsburgh Sleep Quality of Index(PSQI), short form(36) health survey(SF-36), and the Five Facet Mindfulness Questionnaire(FFMQ).

Data management: All retrieval articles will be imported into the EndnoteX9 software. Then, two authors will independently select the articles through reviewing the titles, abstracts and full article according to the inclusion criteria and the exclusion criteria. Excluded studies will be listed in a form with reasons for their exclusion. The selection results will be cross-checked by two authors. Any divarication between two authors will be solved via discussing and negotiating with the third author Firstly, a

standard form will be designed for data collection. Then, two authors will independently extract and record the number in strict accordance with the established form. The standard form consists of general information(such as title, the first author, year of publication), details of study(such as design, inclusion and exclusion criteria, blinding, randomization, and sample size), subject information(such as age and numbers), procedures of intervention(such as type of TAI CHI, exercise duration, intervention time, frequency), types of outcomes(such as primary, secondary, and diverse events), and other detailed information. When there is a disagreement, two authors will discuss and negotiate with the third author to decide. If necessary, we will contact with corresponding authors of the paper to obtain further information.

Quality assessment / Risk of bias analysis: Two authors will assess the bias risk all ultimately included studies by Cochrane Collaboration's tool. The tool includes the following seven components: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, completeness of outcome data, selective outcome reporting and other biases. The assessments for each item be classified as low risk, high risk, and unclear. If there is a lack of information in the study regarding the risk of bias assessment, corresponding authors of the study will be contacted. Disagreement will be settled by discussion.If the included studies beyond 10, the visual asymmetry of funnel plot will apply to analyze potential reporting bias. When funnel plot is unclear, we will perform Egger's test by STATA 11.0 software to quantitative analysis.The Grading of Recommendations Assessment, Development, and Evaluation(GRADE) will be conducted to assess the quality of evidence. The grade of evidence quality is be classified as very low, low, moderate, and high. The summary of results will be summarized in the "Summary of Results" table.

Strategy of data synthesis: Review Manager 5.3 software will be perform for date analysis. The continuous outcomes will be indicated the mean difference (MD) with 95% CI, while dichotomous data will be expressed as RR with 95% CI. When the same outcome measured in different ways, the SMD with 95% CI will be used to express the intervention effect. The Chi-Squared test and I2 statistic will be used to assess heterogeneity. If I2<50%, which means the heterogeneity difference is small among the studies included, the fixed-effect model will be adopted. If I2 ≥ 50% ,which means the heterogeneity difference is significant among the studies included, the random-effects will be adopted.

Subgroup analysis: If the heterogeneity difference is significant, we will conduct a subgroup analysis based on the different treatments in the control group, while a sensitivity analysis to assess the reason of heterogeneity.

Sensitivity analysis: If the heterogeneity difference is significant, we will conduct a subgroup analysis based on the different treatments in the control group, while a sensitivity analysis to assess the reason of heterogeneity.

Language: There are no restrictions on languages.

Country(ies) involved: China.

Keywords: knee osteoarthritis; TAI CHI; protocol; systematic review; meta analysis.

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