

INPLASY PROTOCOL

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The authors declare that there
are no conflicts of interest
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INTRODUCTION

Review question / Objective: This study is to systematically evaluate the efficacy and safety of traditional Chinese medicine

The comparative effectiveness of traditional Chinese medicine exercise therapies in elderly people with mild cognitive impairment: protocol for a network meta-analysis

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Review question / Objective: This study is to systematically evaluate the efficacy and safety of traditional Chinese medicine (TCM) exercise therapies for the treatment of mild cognitive impairment (MCI), including Tai Chi, Baduan jin exercise, Liuzi jue and finger exercise. The network meta-analysis will be used to indirectly compare the four therapies to find out the optimal treatment plan for MCI and to provide evidence-based bias for clinical treatments decision-making. Only randomized controlled trial will be included, and the treatment of control group is routine nursing intervention or other one of the four therapies mentioned above.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 July 2020 and was last updated on 02 July 2020 (registration number INPLASY202070006).

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the four therapies to find out the optimal treatment plan for MCI and to provide evidence-based bias for clinical treatments decision-making. Only randomized controlled trial will be included, and the treatment of control group is routine nursing intervention or other one of the four therapies mentioned above.

Rationale: Meta-analysis summarizes the results of multiple independent studies of the same kind to achieve the purpose of increasing the sample size and improving the test efficiency. Ordinary meta-analysis can only achieve pairwise comparison, but network meta-analysis can achieve indirect comparison of a variety of different intervention approaches, so that some treatment methods that are not directly compared can be indirectly compared to choose the best plan.

Condition being studied: MCI is one of the common functional disorders after stroke or alzheimer disease (AD), which seriously affects the patient's overall recovery. At present, cognitive rehabilitation training is the main means to improve cognitive function, but its curative effect is limited. TCM exercise therapies have been confirmed by several studies to treat MCI with good curative effect and are widely used in China. These therapies mainly include Tai Chi, Baduan jin exercise, Liuzi jue and finger exercise. However, there is still controversy over which therapy is the best for MCI patients. Therefore, it is very necessary to evaluate the safety and effectiveness of these four treatment methods, and use meta-analysis to carry out indirect comparison of these four treatments.

METHODS

Search strategy: The search strategy will include medical subject headings (MeSH) and key words associated with traditional Chinese medicine exercise therapy, Tai Chi, Baduan jin exercise, Liuzi jue and finger exercise in the treatment of MCI. The retrieval time will be set to the time of database-building to July, 2020.

Participant or population: Participants will be elderly people (over 60 years old) who are diagnosed as "mild cognitive impairment" on the Mental State Examination Scale, and sufficient memory and hearing are necessary to receive exercise therapy. There is no restriction on gender, region or race.

Intervention: At least one TCM exercise therapy is implemented, including Tai Chi, Baduan jin exercise, Liuzi jue and finger exercise.

Comparator: Routine nursing intervention or other therapies mentioned above that are different from the intervention group (Tai Chi, Ba duanjin exercise, Liu zijue and finger exercise).

Study designs to be included: Study designs to be included is randomized controlled trials.

Eligibility criteria: 1. Types of Study: randomized controlled trials (RCTs). 2. Participants: participants will be elderly people (over 60 years old) who are diagnosed as "mild cognitive impairment" on mental state examination scales, and sufficient memory and hearing are necessary to receive exercise therapy. There is no restriction on gender, region or race. 3. Interventions: treatment strategies include the following four: Tai Chi, Baduan jin exercise, Liuzi jue and finger exercise. All 4 methods listed above can be used as monotherapy or combined treatments. Controlled interventions will be routine nursing intervention or other therapies mentioned above that are different from the intervention group. Studies that do not meet the inclusion criteria or that are difficult to extract data from will be excluded.

Information sources: We will search publications in the following English and Chinese databases: Web of Science, PubMed, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL), Clinical Trials, China national knowledge infrastructure (CNKI), Wangfang database

and Chinese Biomedical Medicine (CBM) to collect studies.

Main outcome(s): The main outcomes include the Montreal Cognition Assessment Scale (MOCA), the Mini-Mental State Examination (MMSE), the Activity of Daily Living Scale (ADL), Trail Making Test (TMT), etc.

Additional outcome(s): Adverse events, etc.

Data management: Firstly, all the retrieved data will be imported into Endnote X7 software. Two researchers will independently screen and remove the literature that clearly does not meet the inclusion criteria by reading the title and abstract, and eliminate the research that does not meet the requirements, and then carefully read the full text and select the research that meet the requirements. Secondly, we will carefully read the full text of the remaining literature to further decide whether to include or not. Finally, the two researchers will independently extract the data and carefully check it by a third researcher. If there are any disagreements during the data collection process, we will reach agreement through discussion or seek advice from a third party.

Quality assessment / Risk of bias analysis: We will use the RCT bias risk assessment tool recommended by the Cochrane Handbook for Systematic Reviews of Interventions 5.1.0 to perform bias risk assessment and methodological quality assessment of included RCTs. Disagreement will be resolved by a third party.

Strategy of data synthesis: 1. Direct metaanalysis; 2. Network meta-analysis; 3. We will combine the data based on the random-effect model. We will use relative risk (RR) for the dichotomous data, and use standard mean differences (SMD) for the continuous outcome.

Subgroup analysis: Subgroup analyses will be conducted with different types of MCI, gender, age, race, nationality, and duration of medication to explore whether treatment

effects for our primary outcomes are robust.

Sensibility analysis: In the direct comparison, if there is a large heterogeneity and the number of studies included is enough, we will use the method of meta regression for sensitivity analysis, otherwise we will exclude the studies one by one for sensitivity analysis.

Language: No language restrictions.

Country(ies) involved: China.

Other relevant information: None.

Keywords: Traditional Chinese medicine exercise therapy; Tai Chi; Baduan jin exercise; Liuzi jue; Finger exercise; Mild cognitive impairment; Network meta-analysis.

Dissemination plans: Ethical approval is not required for this study, as all analyses were based on previously literature. The findings will be disseminated through conference presentations, media, and peer-reviewed journals.

Contributions of each author:

Author 1 - Kai-qi Su - Drafted the manuscript, responsible for research design, and data analysis.

Author 2 - Su-tong Liu - Drafted the manuscript and formulated the search strategy.

Author 3 - Jie Yuan - Literature search, data extraction and evaluation of bias.

Author 4 - Jie-ying Li - Literature search, data extraction and evaluation of bias.

Author 5 - Rui-qing Li - Provide statistical expertise and guide the extraction of research data and the evaluation of bias.

Author 6 - Xiao-dong Feng - Provide financial support, read and approved the final manuscript.