INPLASY PROTOCOL

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None declared.

Acupuncture and Tuina Therapy for Mild Cognitive Impairment: A Protocol for a Systematic Review and Meta-analysis

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Review question / Objective: **To delineate the evidence base from randomized controlled trials on mild cognitive impairment (MCI) patients with the treatment of acupuncture and tuina therapy.**
Condition being studied: **Mild cognitive impairment (MCI) is an intermediate state between normal aging-induced cognitive decline and dementia. It is characterized by impairment in single or multiple cognitive domains, including memory, executive function, language comprehension and expression, etc. Cognitive function of MCI patients will probably continue to decline and eventually develop into dementia. Early intervention for MCI can reduce the risk of dementia and delay the deterioration of cognitive function. Since drug therapy has no definite efficacy on improving cognitive function of MCI patients at present, non-pharmacological interventions are particularly important in the treatment of MCI. As a representative non-pharmacological intervention in traditional Chinese medicine, acupuncture and tuina therapy is promising in the treatment of MCI.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 April 2023 and was last updated on 01 April 2023 (registration number INPLASY202340001).

INTRODUCTION

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METHODS

Participant or population: Adults with a clinical diagnosis of MCI are the population of interest. The diagnostic criteria must be in accordance with accepted standards such as Peterson criteria (2004), NIA-AA criteria (2011), etc. MCI patients with a definite cause that influence cognitive function, such as cerebrovascular disease, Parkinson's disease, etc., will be excluded.

Intervention: Patients in the experimental group needed to have received at least one type of acupuncture and tuina therapy, including but not limited to acupuncture, electroacupuncture, moxibustion, massage, auricular point sticking, finger needling, etc. Acupuncture and tuina therapy could be used alone or in combination with other non-pharmacological interventions for enhancing cognitive function such as cognitive training, transcranial direct current stimulation, etc. At the same time, the intervention of the experimental group could be combined with the same therapy as the control group, e.g., acupuncture + cognitive training / cognitive training. Studies with drug therapy or dietary supplement targeted to improve cognitive function in the experimental group will be excluded.

Comparator: The population of the control group must be diagnosed with MCI. Interventions of the control group could be treatments without acupuncture and tuina therapy, sham intervention, health education, blank or waiting group.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: The inclusion criteria were as follows: (1) Population: Adults clinically diagnosed with MCI. The diagnostic criteria must be in accordance with accepted standards such as Peterson criteria (2004), NIA-AA critieria (2011), etc. (2) Intervention: ①At least one type of acupuncture and tuina therapy, including but not limited to acupuncture, electroacupuncture, moxibustion, massage, auricular point sticking, finger needling, etc. ②Acupuncture and tuina therapy could be used alone or in combination with other non-pharmacological interventions for enhancing cognitive function such as cognitive training, transcranial direct current stimulation, etc. (3) Comparison: Interventions of the control group could be treatments without acupuncture and tuina therapy, sham intervention, health education, blank or waiting group. And the studies must contain MCI adults only. (4) Outcomes: Including at least one of following outcomes: ①Montreal cognitive assessment (MoCA); ②Mini-mental state examination (MMSE); ③Activities of daily living (ADL). (5) Study Design: ①Randomized controlled trial. ②The language should be limited to Chinese and English.The exclusion criteria were as follows: (1) Population: ①Mixed samples of MCI patients and other populations, e.g., healthy population and dementia patients. ②Secondary cognitive impairment due to severe brain organic lesions, mental disorders, drug or alcohol dependence, etc. (2) Intervention: Studies with drug therapy or dietary supplement targeted to improve cognitive function in the experimental group will be excluded. (3) Comparison: ①The control group does not include the therapy combined with the experimental group, e.g., acupuncture + cognitive training / blank group. ②The intervention of

the control group falls under the category of acupuncture and tuina therapy. (4) Outcomes: The scores of the outcome indicators between the experimental group and the control group have significant differences at baseline ($P<0.05$). (5) Study Design: ①Non-Chinese or non-English literature; ②Non-RCT trials; ③Literature with no access to valid data; ④Non-core journal literature, summary of conference papers, academic dissertations and reviews; ⑤Animal experiments; ⑥Literature not ethically cleared; ⑦Duplicate publication or data.

Information sources: Pubmed, Cochrane Library, CNKI, VIP, Wanfang Data and CBM.

Main outcome(s): At least one authority neuropsychological scale such as MoCA, MMSE, ADL, etc.

Additional outcome(s): According to practical situation, we will select other scales, biomarker test results and neuroimaging results.

Quality assessment / Risk of bias analysis: The risk of bias of each study in this review will be assessed using the Cochrane Handbook for Systematic Reviews of Interventions. Random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias will be evaluated as low, unclear, or high risk of bias.

Strategy of data synthesis: We will pool data whenever possible and appropriate. If we judge meta-analyses unsuitable, we will use a narrative description. If we judge meta-analyses suitable, we will use Review Manager (Revman) version 5.4.1 to analyze the research data. Regarding to continuous variables, mean difference (MD) will be selected as the combined statistics, and each effect quantity will be expressed with 95% CI. Analysis will be carried out using a fixed or random effects model according to the heterogeneity. The level of heterogeneity in the study depends on the I^2 statistic, larger values indicating increased heterogeneity. $P < 0.1$ will be regarded as statistical heterogeneity and prompts random effects modelling after excluding the influence of obvious heterogeneity.

Subgroup analysis: If necessary, each of the outcomes will be conducted subgroup such as moxibustion group, electroacupuncture group, etc.

Sensitivity analysis: Sensitivity analysis will be used to assess the robustness of the meta-analysis results and will be performed if there is significant heterogeneity among studies.

Country(ies) involved: China.

Keywords: Mild cognitive impairment; acupuncture; tuina; systematic review.

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