INPLASY PROTOCOL

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The authors have no conflicts of interest to disclose.

Moxibustion for the Treatment of Alzheimer's Disease：A protocol for a systematic reviews and meta-analysis

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Review question / Objective: **Can moxibustion therapy improve quality of life in Alzheimer's disease patients?**
Condition being studied: **Alzheimer's disease (AD) occurs in the elderly and the early stage of aging, with early clinical manifestations of memory impairment, cognitive impairment, behavioral change and decline in language function, etc., and eventually loss of the ability to live independently, requiring 24-hour care, and a variety of complications. However, these complications are the direct cause of death in Alzheimer's disease patients. With the acceleration of the aging process of society, the incidence of Alzheimer's disease is increasing year by year, seriously threatening the physical health and quality of life of the elderly. There are many ways to treat Alzheimer's disease, however, moxibustion is especially popular in China. Therefore, our systematic review aims to evaluate the efficacy and safety of moxibustion in the treatment of Alzheimer's disease and to provide reliable evidence for clinical decision makers.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 6 January 2021 and was last updated on 6 January 2021 (registration number INPLASY202110021).

INTRODUCTION

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METHODS

Search strategy: We will search PubMed, Embase, Cochrane Library, China Biomedical Literature Database(CBM), China National Knowledge Infrastructure(CNKI), Wanfang Database(WF), and China Scientific Journals Database(VIP) (up to January 2021) in Chinese and English language.Search terms of disease: senile dementia, Alzheimer's disease, presenile dementia, Alzheimer syndrome, Alzheimer sclerosis; and intervention: moxibustion, moxa, suspended moxibustion, mild moxibustion, needle warming moxibustion, thunder fire needle, thunder fire god moxibustion, wheat-sized moxibustion, ginger partitioned moxibustion, governor vessel moxibustion; and research type: randomized controlled trial, controlled clinical trial, randomized.

Participant or population: Participants are Alzheimer's disease patients.

Intervention: Moxibustion therapy is an intervention which help in the memory, cognitive, behavioral of Alzheimer's disease patients during the therapy.

Comparator: Participants without moxibustion therapy.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: RCTs assessing moxibustion treatment for AD will be eligible for inclusion and were published in English or Chinese, with the full-text available. AD patients with definite diagnostic criteria will be included.

Information sources: We will search PubMed, Embase, Cochrane Library, China Biomedical Literature Database(CBM), China National Knowledge Infrastructure(CNKI), Wanfang Database(WF), and China Scientific Journals Database(VIP) (up to January 2021).If there are any problems with the study, we will try to contact the author.

Main outcome(s): Mini-mental state examination(MMSE). Activity of daily living scale(ADL). Alzheimer disease assessment scale-cog(ADAS-cog). Montreal cognitive assessment(MoCA).

Additional outcome(s): Side effects.

Quality assessment / Risk of bias analysis: The risk of bias assessment tool recommended by Cochrane Collaboration Network was used to evaluate the quality of included studies.Including the following 7 evaluation items:(1)random sequence generation;(2)allocation concealment;(3)blinding of participants and personnel;(4)blinding of outcome assessment;(5)incomplete outcome data;(6)selective reporting;(7)other sources of bias. For each study, the results were rated as "Yes"(low risk),"No"(high risk) and "unclear"(lack of relevant information or uncertainty about bias) for zbove seven items. Two reviewers independently performed quality assessment and all disagreements will be resolved by discussion.

Strategy of data synthesis: We will used RevMan V.5.3 software for statistical analysis. For continuous variables, when outcomes were measured by the same scale, the results were reported as standardized mean difference(MD) and 95% confidence interval(CI);when different scales were used, the results were reported as standardized mean difference (SMD) and 95% CI. Categorical data will be calculated with the risk ratio(RR) and 95% CI. We will use I^2 test and χ^2 test to evaluate the heterogeneity of the results. When I^2 0.10, the results of the study will be

considered as homogeneous, and fixed effect model will be used; otherwise, random effect model will be used.

Subgroup analysis: If the necessary data are available, subgroup analyses will be done by differences of control group.

Sensibility analysis: When there are sufficient RCTs, we will conduct sensitivity analysis based on methodological quality, sample size and missing data to evaluate the robustness of the research results.

Language: Chinese and English.

Country(ies) involved: China.

Keywords: moxibustion, Alzheimer's disease, protocol, systematic review.

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