

INPLASY PROTOCOL

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None declared.

Efficacy and safety of moxibustion for senile insomnia: A protocol of systematic review and meta-analysis

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Review question / Objective: Insomnia is common in older adults, and half of them have sleep problems. The incidence rate of insomnia in elderly people is between 30% and 60%. Insomnia is also correlated with coronary heart disease, hypertension, and depression, which can increase the risk of death, seriously affect the health of patients, and increase the burden on society. Current treatments for insomnia have limitations and patients are prone to relapse after being cured. **P:**Patients (≥ 60 years old) were clinically diagnosed with insomnia. **I:**Moxibustion or moxibustion combined with other treatments. **C:**The control group took any treatment except moxibustion. **O:**The efficacy of moxibustion in the treatment of insomnia. **S:**Randomized controlled trials (RCTs).

Information sources: We will search for randomized controlled studies in the following databases: PubMed, Embase, The Cochrane Library, Web of science, China National Knowledge Infrastructure (CNKI), Wanfang, China Science and Technology Journal Database (VIP), Chinese BioMedical Literature Database (CBM). Searches of the above databases were conducted from the time the databases were created until March 2022, regardless of region and language.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 April 2022 and was last updated on 01 April 2022 (registration number INPLASY202240002).

INTRODUCTION

Review question / Objective: Insomnia is common in older adults, and half of them have sleep problems. The incidence rate of insomnia in elderly people is between 30%

and 60%. Insomnia is also correlated with coronary heart disease, hypertension, and depression, which can increase the risk of death, seriously affect the health of patients, and increase the burden on society. Current treatments for insomnia

have limitations and patients are prone to relapse after being cured. P:Patients(≥ 60 years old) were clinically diagnosed with insomnia. I:Moxibustion or moxibustion combined with other treatments. C:The control group took any treatment except moxibustion. O:The efficacy of moxibustion in the treatment of insomnia. S: Randomized controlled trials (RCTs).

Condition being studied: The clinical symptoms of insomnia are: 1. decreased sleep quality, 2. difficulty in falling asleep, 3. excessive dreaming, 4. lack of sleep depth, 5. early awakening, and 6 insufficient sleep duration. Moxibustion is a traditional Chinese medical treatment with a long history. There are two types of moxibustion: direct moxibustion, and indirect moxibustion. The study will evaluate the efficacy and safety of moxibustion for senile insomnia.

METHODS

Participant or population: Patients(≥ 60 years old) were clinically diagnosed with insomnia.

Intervention: Moxibustion or moxibustion combined with other treatments.

Comparator: The control group took any treatment except moxibustion.

Study designs to be included: Randomized controlled trials (RCTs).

Eligibility criteria: Inclusion criteria: 1.Study type must be a randomized controlled study.2.Patients must be ≥ 60 years old.3. Patients are clinically diagnosed with insomnia.Exclusion criteria: 1. The type of study is not a randomized controlled study .2. The sample size is too small.

Information sources: We will search for randomized controlled studies in the following databases: PubMed, Embase, The Cochrane Library, Web of science, China National Knowledge Infrastructure (CNKI), Wanfang, China Science and Technology Journal Database (VIP),

Chinese BioMedical Literature Database (CBM). Searches of the above databases were conducted from the time the databases were created until March 2022, regardless of region and language.

Main outcome(s): To observe the efficacy of moxibustion in the treatment of insomnia, using clinical efficiency as an indicator.

Additional outcome(s): Sleep quality assessed with the Pittsburgh Sleep Quality Index(PSQI).

Quality assessment / Risk of bias analysis: Risk of study bias was assessed using the cochrane risk of bias assessment tool and Revman. Six aspects were assessed according to: random assignment method, assignment scheme, blinding, data integrity, selective reporting of study results, and other sources of bias. The included literature was classified into three levels according to the assessment criteria: bottom risk, high risk, and unclear.

Strategy of data synthesis: Heterogeneity of the study results was tested with I^2 . If $P < 0.1$ and $I^2 \geq 50\%$, it indicates significant heterogeneity of study results, and the random-effects model was selected to merge the data. If $P \geq 0.1$ and $I^2 < 50\%$, the heterogeneity was not significant, and the fixed-effects model was selected to merge the data.The dichotomous data effect size was expressed as the relative risk (RR) with 95% confidence interval (CI).Continuous variables data effect sizes were expressed as mean difference (MD) or Standardized mean difference(SMD) with 95 % confidence interval (CI).

Subgroup analysis: If there was significant heterogeneity in the study results, subgroup delineation was performed. Subgroup division was based on gender, duration of disease, duration of treatment, type of moxibustion, and comparison of moxibustion with other treatment options.

Sensitivity analysis: Sensitivity analysis was performed on the study results to ensure the stability of the study findings. The

sensitivity analysis was considered to be passed if any of the included papers were excluded and the remaining data were combined, and the study findings were not affected.

Country(ies) involved: China.

Keywords: moxibustion, senile insomnia, systematic review.

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