

INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Efficacy and safety of acupuncture for senile insomnia: a protocol of systematic review and meta-analysis

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Review question / Objective: Is acupuncture efficacy and safety for senile insomnia?

Condition being studied: Senile insomnia.

Eligibility criteria: ①Patients (≥60 years) with senile insomnia regardless of any age and gender; ②Randomized controlled trials (RCTs) of acupuncture for senile insomnia which were published in English and Chinese will be included; ③In the treatment group, acupuncture was used alone or combined with other therapies, while in the control group, acupuncture was not included; ④Primary outcome: Pittsburgh sleep quality index (PSQI). The insomnia severity index, (ISI).

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 June 2021 and was last updated on 28 June 2021 (registration number INPLASY202160106).

INTRODUCTION

Review question / Objective: Is acupuncture efficacy and safety for senile insomnia?

Condition being studied: Senile insomnia.

METHODS

Participant or population: Patients who received acupuncture for senile insomnia.

Intervention: Acupunctue.

Comparator: Anyother treatment except acupuncture.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: ①Patients (≥ 60 years) with senile insomnia regardless of any age and gender;②Randomized controlled trials (RCTs) of acupuncture for senile insomnia which were published in English and Chinese will be included;③In the treatment group, acupuncture was used alone or combined with other therapies, while in the control group, acupuncture was not included;④Primary outcome: Pittsburgh sleep quality index (PSQI). The insomnia severity index,(ISI)

Information sources: We will search Chinese and English databases : China National Knowledge Infrastructure (CNKI), Chinese Scientific and Journal Database (VIP), Wan Fang database(Wan fang), Chinese Biomedical Literature Database (CBM), PubMed, EMBASE, Cochrane library to identify articles of RCTs of acupuncture for senile insomnia.

Main outcome(s): Pittsburgh sleep quality index (PSQI). The insomnia severity index, (ISI).

Quality assessment / Risk of bias analysis: Two researchers will evaluate the bias risk of the included studies with the risk assessment tool of RCT bias recommended by Cochran Collaboration Network Bias Risk Assessment Tool. When disagreements arise, seek a third researcher to negotiate.

Strategy of data synthesis: We will use Revman 5.3 software for meta-analysis. We will use relative risk (RR) as the effect index for the count data, mean difference (MD) will be used for the measurement data as the effect index. The confidence interval (CI) of each effect index was set to 95%. At the same time, the heterogeneity will be quantitatively assessed with I². If there was no statistical heterogeneity among the

studies, the fixed effect model will be used for meta-analysis; If there is heterogeneous, the random effects model will be used. $P < 0.05$ indicates statistical significance.

Subgroup analysis: When there is some potential heterogeneity in this study, we may conduct subgroup analysis according to the genders, different ages and different treatment times of included participants, if all the information could be available from included studies.

Sensitivity analysis: Sensitivity analysis will be conducted for assessing the robustness of the included results. Studies of high-risk bias will be excluded, If the results are unstable.

Language: English and Chinese.

Country(ies) involved: China.

Keywords: acupuncture, meta-analysis, Lianhua Qingwen, senile insomnia.

Contributions of each author:

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