

INPLASY PROTOCOL

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Corresponding author:
Biqing Huang

1032159472@qq.com

Author Affiliation:
Chengdu University of TCM

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None.

The effect of acupuncture on emotional disorders in patients with insomnia: a systematic review protocol

Xu, GX¹; Luo, L²; Huang, BQ³.

Review question / Objective: whether acupuncture therapy is effective in improving the emotional health of patients with insomnia?

Condition being studied: Insomnia is a bio-behavioral disorder characterized by and accompanied by difficulty in falling asleep, dreaminess, and restless sleep; associated symptoms (fatigue, cognition and memory complaint, Daytime behavior disorder and so on). Insomna affects about 23.2% of adult population in the United States and up to 45.4% in China, which is a risk factor for stroke, hypertension, mental disorders. Chronic insomnia is frequently accompanied by emotional disorders, which can exert a major negative effect on the quality of life in patients with insomnia. Emotional disorders have been shown associated with insomnia influencing disease prevalence, treatment and clinical outcomes. Therefore, holistic therapy is needed to enhance the treatment outcomes. Acupuncture has been shown to have the effects on insomnia and insomnia-related emotion disorders.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 October 2020 and was last updated on 29 October 2020 (registration number INPLASY2020100115).

INTRODUCTION

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adult population in the United States and up to 45.4% in China, which is a risk factor for stroke, hypertension, mental disorders. Chronic insomnia is frequently accompanied by emotional disorders, which can exert a major negative effect on the quality of life in patients with insomnia. Emotional disorders have been shown associated with insomnia influencing disease prevalence, treatment and clinical outcomes. Therefore, holistic therapy is needed to enhance the treatment outcomes. Acupuncture has been shown to have the effects on insomnia and insomnia-related emotion disorders.

METHODS

Participant or population: Patients who meet internationally recognized diagnostic criteria for insomnia will be included regardless of age, sex and source of cases. And patients need to be accompanied by a certain degree of emotional disorder: pathological anxiety and depression (secondary to insomnia).

Intervention: Body acupuncture (manual/electro), auricular acupuncture, laser acupuncture, warm needling and so on.

Comparator: Pharmacotherapy, cognitive-behavioral therapy (CBI), placebo.

Study designs to be included: RCTs.

Eligibility criteria: Criteria for including studies in this review Types of studies RCTs of acupuncture therapy for insomnia with anxiety or depression, which were reported in Chinese or English, will be included. The types of randomized including randomization numbers by random number table, envelope or other methods. Quasi-RCTs and uncontrolled clinical trials will be excluded. Types of participants Patients were diagnosed primary insomnia, will be included regardless of the age, gender, source, and short-term or chronic insomnia in cases. The guideline of insomnia is unlimited, like International Classification of Sleep DisordersII/III (ICSD-2/ICSD-3) or Chinese guideline of insomnia disorder diagnosis and its treatment. Types of

intervention The intervention of interest is needle stimulation of acupoints, including body acupuncture (manual/electro), auricular acupuncture and scalp acupuncture, and regardless of course and frequency of treatment. Comparator(s)/control The comparators of the studies are unlimited but studies comparing different acupoints or different forms of acupuncture will be excluded.

Information sources: The following seven databases will be searched from inception to March2020: Cochrane Central Register of Controlled Trials (CENTRAL), PubMed, EMBASE, China National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM), VIP Database and Wanfang Database.

Main outcome(s): Emotion-related assessment scale: Hamilton Depression Scale (HAMD), Hamilton Anxiety Scale (HAMA), et al.

Additional outcome(s): 1. Pittsburgh Sleep Quality Index (PSQI) 2. Insomnia Severity Index (ISI).

Data management: Two reviewers will independently extract the data. We will collect the following information using a standard form: author information, year of publication, participant characteristics (such as average age, gender) and details of the intervention and comparison etc. Disagreements will be resolved by the third reviewer.

Quality assessment / Risk of bias analysis: Two review authors will independently evaluate the risk of bias by using the Cochrane Collaboration's risk-of-bias assessment method. The following domains will be accessed for risk of bias: sequence generation; allocation concealment; blinding of participants and personnel; blinding of outcome assessors; incomplete outcome data; selective reporting and other issues. The assessments of trials will be categorized as three levels: unclear risk, low risk and high risk. Disagreements will be resolved by the third reviewer.

Strategy of data synthesis: Meta-analysis will be performed using RevMan software. Continuous data will be presented as the mean differences (MDs) with a 95% confidence interval (CI), whereas dichotomous data will be presented as relative risk (RR) with a 95% CI. A standard χ^2 test with a significance level of $p < 0.1$ will be used for testing statistical heterogeneity. An I^2 test will be used for quantifying inconsistency among the included studies. Study will not be considered to have heterogeneity when the I^2 value is less than 50%. Heterogeneous data will be pooled using the random-effects model.

Subgroup analysis: If possible, subgroup analysis will be performed based on the following: 1. the type of acupuncture. 2. the type of control intervention. 3. the measuring time points of outcomes. 4. the age groups of population.

Sensitivity analysis: A sensitivity analysis will be conducted to monitor the robustness and examine the potential influence through excluding studies from the analysis one by one. We will take care of some decision nodes, such as sample size, the weakness of methodological and missing data.

Language: English.

Country(ies) involved: China.

Keywords: insomnia, emotional disorders, acupuncture, anxiety, depression.

Contributions of each author:

Author 1 - Guixing Xu.

Author 2 - Ling Luo.

Author 3 - Biqing Huang.