INPLASY PROTOCOL

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Review Stage at time of this submission: The review has not yet started.

Conflicts of interest: None.

Study on Acupuncture improving Depression and anxiety in patients with Insomnia based on rs-fMRI: a protocol for systemic review and meta-analysis

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Review question / Objective: Acupuncture can effectively improve the symptoms of depression and anxiety in patients with insomnia, but its specific mechanism still needs to be further explored. Multi-modal brain imaging is the most widely used method to study the neural mechanism at present. In this study, meta-analysis will used to integrate and analyze the values of ALFF and Reho, and to explore the characteristics and rules of acupuncture on the changes of brain activity in patients with depression and anxiety symptoms of insomnia, in order to provide effective evidence for the elucidation of its pathogenesis.

INTRODUCTION

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evidence for the elucidation of its pathogenesis.

Condition being studied: Sleep is a universal function of living species, comprising 1/3 of human life. The incidence rate of insomnia is increasing year by year with the increasing pressure of external factors such as society, environment and working mode. Especially for medical workers who are engaged in high load and shift work, the proportion of sleep is seriously unbalanced, which is more likely to lead to sleep problems such as insomnia, resulting in the decline of work efficiency and the increase of error rate. How to reduce the impact of insomnia and other sleeping trouble on the emotion, learning, memory of medical workers, and improve the quality of medical service, has become a key problem to be solved urgently. At present, relevant clinical studies have confirmed that acupuncture can significantly improve depression and anxiety caused by insomnia. Multi-modal brain imaging technology is an important means to study the neural mechanism, and there have been studies on the application of multi-modal brain imaging technology to explore the mechanism of acupuncture on depression and anxiety symptoms in patients with insomnia. However, the results of relevant studies reported are quite different, so it is necessary to integrate and analyze the existing studies by using meta-analysis.

METHODS

Participant or population: Patients who meet domestic and 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: Manual-acupuncture and electro-acupuncture.

Comparator: Pharmacotherapy, sham-acupuncture, placebo or rehabilitation exercise therapy.

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

Eligibility criteria: 1.Types of studies: We will include RCTs reporting, languages and publication categories are not limited. We will exclude Non-RcTs reviews animal experimental studies case report, expert experience, conference article and duplicated publications. 2.Types of participants: Participants diagnosed with insomnia and accompanied by a certain degree of emotional disorder pathological anxiety and depression will be included, regardless of age, race, duration of disease, weight, mode of delivery, or education. 3. Types of interventions: Manual-acupuncture and electro-acupuncture£Ĵregardless of needling techniques and stimulation method. we will rule out interventions without stimulating the acupoint. 4. Types of control groups: Treatments in the comparison groups can be Pharmacotherapy, sham-acupuncture, placebo or rehabilitation exercise therapy. Studies compared different type of acupuncture methods will be included.

Information sources: The following nine databases will be searched from inception to January 2021£şPubMed, EMBASE, EBSCOhost-medline, Web of Science, Cochrane Library, China National Knowledge Infrastructure(CNKI), VIP Database and Wanfang Database£Ĵ Chinese Biomedical Literature Database(CBM).

Main outcome(s): Pittsburgh Sleep Quality Index(PSQI), Hamilton Depression Scale(HAMD), Hamilton Anxiety Scale(HAMA), Regional homogeneity (ReHo), Amplitude of low-frequency fluctuations(ALFF), Region of interest(ROI).

Quality assessment / Risk of bias analysis: According to the bias risk assessment tool of RCT in 5.1 of Cochrane system reviewer's Handbook, the bias risk of included literatures was evaluated by 2 reviewers independently evaluated each of the following items as "high", "low" and "unclear": (1) the generation of random sequences; (2) allocation concealment; (3)

blind implementation of researchers and subjects; (4) blind implementation of outcome indicators; (5) the integrity of outcome data; (6) selective reporting of research results; (7) other sources of bias.

Strategy of data synthesis: Revman5.3 and stata13.1 were used for meta-analysis. The count data were represented by relative risk (RR) and continuous variables by standardized mean difference (SMD). 95% confidence interval (95% CI) was calculated for both. The heterogeneity of the included studies was judged by I2 value, with P<0.05 as the statistical difference. I2 values of 0~24.9%, 25%~49.9%, 50%~74.9%, and 75%~100% respectively indicate zero, low, medium, and high heterogeneity. When pHŬ0.10 and I2<50%, fixed effect model was used to analyze the heterogeneity. Otherwise, meta regression analysis was used to analyze the source of heterogeneity. If clinical heterogeneity could not be excluded, random effect model (mantel ˇC Haenszel) was selected. The bias of the study was analyzed by Egger's test and funnel plot (P<0.05).

Subgroup analysis: If the necessary data are available, subgroup analysis will be carried out according to different factors as follows£şcontrol interventions; acupoints selecting; acupuncture manipulation.

Sensibility analysis: If the necessary data are available, subgroup analysis will be carried out according to different factors as follows£şcontrol interventions; acupoints selecting; acupuncture manipulation.

Language: Chinese and English.

Country(ies) involved: China.

Keywords: Acupuncture, insomnia, depression, anxiety, Resting-state functional magnetic resonance, meta-analysis.

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