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None declared.

Acupuncture and Related Therapies for Post-stroke Insomnia: A Protocol for Systematic Review and Network Meta-analysis

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Review question / Objective: To compare and rank the clinical effects of different acupuncture and acupuncture-related therapies on patients with post-stroke insomnia.

Condition being studied: The long-term insomnia of stroke patients will not only aggravate the psychological burden, affect the therapeutic effect, but also may further develop into anxiety, depression, heart disease, hypertension and so on, which may induce stroke again. Studies had shown that non-drug therapies such as acupuncture, moxibustion, auricular acupoint stimulation, and transcranial magnetic stimulation have good effects on patients with insomnia. With the increasing incidence of stroke, the number of patients suffering from insomnia after stroke is also increasing. In view of the shortcomings of drug treatments, there are more and more reports of post-stroke insomnia patients using non-drug treatments with acupuncture as the main adjunct therapy, confirming the role of acupuncture in stroke and insomnia. However, due to the wide variety of acupuncture and the different focus on efficacy, there is still a lack of direct comparative studies between different acupuncture-related therapies. In this study, the network Meta-Analysis (NMA) method was used to evaluate the effects of various acupuncture-related therapies for patients with Post-stroke Insomnia, expected to provide evidence-based medicine evidence for selecting the best combination of options.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 February 2021 and was last updated on 07 February 2021 (registration number INPLASY202120028).

INTRODUCTION

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acupuncture and acupuncture-related therapies on patients with post-stroke insomnia.

Condition being studied: The long-term insomnia of stroke patients will not only aggravate the psychological burden, affect the therapeutic effect, but also may further develop into anxiety, depression, heart disease, hypertension and so on, which may induce stroke again. Studies had shown that non-drug therapies such as acupuncture, moxibustion, auricular acupoint stimulation, and transcranial magnetic stimulation have good effects on patients with insomnia. With the increasing incidence of stroke, the number of patients suffering from insomnia after stroke is also increasing. In view of the shortcomings of drug treatments, there are more and more reports of post-stroke insomnia patients using non-drug treatments with acupuncture as the main adjunct therapy, confirming the role of acupuncture in stroke and insomnia. However, due to the wide variety of acupuncture and the different focus on efficacy, there is still a lack of direct comparative studies between different acupuncture-related therapies. In this study, the network Meta-Analysis (NMA) method was used to evaluate the effects of various acupuncture-related therapies for patients with Post-stroke Insomnia, expected to provide evidence-based medicine evidence for selecting the best combination of options.

METHODS

Participant or population: Patients were required to have passed the acute phase and had clear diagnostic criteria to be diagnosed with post-stroke insomnia or post-stroke sleep disorders.

Intervention: Interventions in the treatment group included were various types of acupuncture-related therapies, including simple acupuncture (ACU), electroacupuncture (EA), warm acupuncture (WA), auricular acupoint stimulation (AAS), acupuncture injection (AI), acupoint catgut embedding (ACE), or a combination of acupuncture and drugs.

Comparator: The control group is various western medicines with sleep aids or

comparison between various acupuncture-related therapies.

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

Eligibility criteria: The published randomized controlled trials (RCT) of acupuncture-related therapies for the treatment of post-stroke insomnia, regardless of age and gender. Patients were required to have passed the acute phase and had clear diagnostic criteria to be diagnosed with post-stroke insomnia or post-stroke sleep disorders. Interventions in the treatment group included were various types of acupuncture-related therapies, including simple acupuncture (ACU), electroacupuncture (EA), warm acupuncture (WA), auricular acupoint stimulation (AAS), acupuncture injection (AI), acupoint catgut embedding (ACE), or a combination of acupuncture and drugs; the control group is various western medicines with sleep aids, or comparison between various acupuncture-related therapies. The results of report are required to include at least one of the following outcome indicators: Pittsburgh sleep quality index (PSQI), Insomnia Severity Index (ISI), Self-Rating Anxiety Scale (SAS), and Self-Rating Depression Scale (SDS). The language of the publication is limited to Chinese or English.

Information sources: Our literature search was performed from database establishment until Feb 1st, 2021, including three English databases: PubMed, EMBASE, Cochrane Library, and four Chinese databases: the China Biology Medicine (CBM), the China National Knowledge Infrastructure (CNKI), Wanfang Data, the Chinese Scientific Journal Database (VIP). The search was conducted using a combination of medical subject headings (MeSH) terms and free words. In addition, the references included in the medical literature were retrospectively supplemented to obtain the associated references.

Main outcome(s): Outcome indicators: Effectiveness Rate, Pittsburgh sleep quality index (PSQI), Insomnia Severity Index (ISI), Self-Rating Anxiety Scale (SAS), and Self-Rating Depression Scale (SDS). The language of the publication is limited to Chinese or English.

Quality assessment / Risk of bias analysis: Two researchers evaluated the included studies in accordance with the bias risk assessment tool recommended in the Cochrane Handbook 5.1.

Strategy of data synthesis: Statistical analysis was performed using Stata 15.0 and WinBUGS 1.4.3 software. The effectiveness rate was categorically variable, and its effect size was estimated using the risk ratio (RR). However, the PSQI, ISI, SAS, SDS scores were numerical variables, thus the differences in the effect amount before and after treatment were used as the effect size. In some trials, the change between baseline and after treatment failed to show, and the missing data was estimated using the formula recommended by the Cochrane Handbook 5.1. First, Stata15.0 was used to draw an NMA evidence relationship diagram (Metan, Network Meta-Analysis, Metareg package), if the literature is three-arm or more, it is split and reconstituted into all paired two-arm tests. Second, WinBUGS 1.4.3 was run to set the number of iterations to 50 000 for NMA; 95% confidence interval (95% CI) of inconsistency factors (IF) was used to judge the consistency of the closed-loop. If the IF with 95% CI contains 0, it means that the direct and indirect evidence is consistent; otherwise, it means that there is a higher possibility of inconsistency. Third, the Stata 15.0 program was applied to create funnel plots to determine whether there was evidence of small sample effects in the included studies. Last, the surface under the cumulative ranking curve (SUCRA) was generated using Stata 15.0 to show the SUCRA scores for all interventions, with higher SUCRA scores implying higher treatment class.

Subgroup analysis: We perform subgroup analysis based on different outcome indicators.

Sensitivity analysis: The main methods of sensitivity analysis are excluding low-quality studies, using different statistical methods models to analyze the same data, etc.

Language: The language of the publication is limited to Chinese or English.

Country(ies) involved: China.

Keywords: Pittsburgh sleep quality index(PSQI), Insomnia Severity Index(ISI), Self-Rating Anxiety Scale(SAS), and Self-Rating Depression Scale(SDS).

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