

# INPLASY

## Efficacy of acupuncture combined with low-frequency repetitive transcranial magnetic stimulation in the treatment of patients with insomnia: a systematic review and Meta-analysis

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### ADMINISTRATIVE INFORMATION

**Support** - None.

**Review Stage at time of this submission** - Preliminary searches.

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY202470001

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 July 2024 and was last updated on 01 July 2024.

### INTRODUCTION

**Review question / Objective** Acupuncture combined with low-frequency repetitive transcranial magnetic stimulation (LF-rTMS) has been considered an effective technique for the treatment of insomnia in many studies. However, due to limited clinical data, the efficacy of polysomnography (PSG) versus the Pittsburgh Sleep Quality Index (PSQI) on sleep architecture remains unclear. Therefore, the aim of this meta-analysis was to assess the efficacy of LF-rTMS combined with acupuncture based on PSG reports with PQSI.

P: Insomniacs

I: Acupuncture combined with low frequency transcranial magnetic stimulation

C: sham LF-rTMS combined with acupuncture or sham acupuncture combined with LF-rTMS or medication alone

O: PSQI, PSG, clinical outcome

S: RCT.

**Condition being studied** Acupuncture and Low-Frequency Repetitive Transcranial Magnetic Stimulation (LF-rTMS) are two different therapeutic approaches that each have unique mechanisms and indications. Acupuncture is a traditional Chinese medicine treatment that regulates the balance of qi and blood by stimulating specific points on the body to improve body functions. On the other hand, rTMS, a non-invasive physical therapy, produces pulsed magnetic fields that modify the membrane potential of nerve cells in the cerebral cortex. This, in turn, influences the electrical activity of nerve tissue and brain metabolism. In recent years, some studies have explored the possibility of combining acupuncture and rTMS in the treatment of insomnia. However, none of them have systematically evaluated whether the efficacy of the combined treatment is more significant. Given that the Pittsburgh Sleep Quality Index (PSQI) is a reliable rating scale for sleep quality and that polysomnography (PSG) is the most reliable examination technique for sleep structure, the present study investigated the clinical efficacy of the combination of LF-rTMS

with acupuncture therapy in patients with insomnia through a systematic review of the literature and meta-analysis.

## METHODS

**Search strategy** (low-frequency repetitive transcranial magnetic stimulation) AND (((((((((((Acupuncture[MeSH]) OR (Acupuncture)) OR (Moxibustion)) OR (Needle)) OR (Electroacupuncture)) OR (Electro-acupuncture)) OR (Needle warming moxibustion)) OR (Scalp acupuncture)) OR (Abdominal acupuncture)) OR (Body acupuncture)) AND (((((((((((Magnetic Stimulation, Transcranial[Title/Abstract]) OR (Magnetic Stimulation, Transcranial[Title/Abstract])) OR (Stimulations, Transcranial Magnetic[Title/Abstract])) OR (Stimulation, Transcranial Magnetic[Title/Abstract])) OR (Transcranial Magnetic Stimulation[Title/Abstract])) OR (Transcranial Magnetic Stimulation, Paired Pulse[Title/Abstract])) OR (Transcranial Magnetic Stimulation, Repetitive[Title/Abstract])) OR (Transcranial Magnetic Stimulation, Single Pulse[Title/Abstract])) OR ("Transcranial Magnetic Stimulation"[Mesh]))) AND (((((((((((((((DIMS (Disorders of Initiating[Title/Abstract] AND Maintaining Sleep[Title/Abstract]) OR (Disorders of Initiating[Title/Abstract] AND Maintaining Sleep[Title/Abstract]) OR (Sleeplessness[Title/Abstract]) OR (Insomnia Disorder\*[Title/Abstract]) OR (Insomnia\*[Title/Abstract]) OR (Chronic Insomnia[Title/Abstract]) OR (Insomnia, Chronic[Title/Abstract]) OR (Early Awakening[Title/Abstract]) OR (Awakening, Early[Title/Abstract]) OR (Nonorganic Insomnia[Title/Abstract]) OR (Insomnia, Nonorganic[Title/Abstract]) OR (Primary Insomnia[Title/Abstract]) OR (Insomnia, Primary[Title/Abstract]) OR (Psychophysiological Insomnia[Title/Abstract]) OR (Insomnia, Psychophysiological[Title/Abstract]) OR (Rebound Insomnia[Title/Abstract]) OR ("Sleep Initiation and Maintenance Disorders"[Mesh]))))

**Participant or population** Adults (age >18 years) who meet the diagnostic criteria for insomnia, regardless of their gender or race.

**Intervention** Acupuncture combined with low-frequency repetitive transcranial magnetic stimulation.

**Comparator** Comparison with sham LF-rTMS combined with acupuncture or sham acupuncture combined with LF-rTMS or medication alone. Other treatments (if any) should be the same as the intervention.

**Study designs to be included** RCT.

**Eligibility criteria** Inclusion criteria: (1) In order to treat insomnia, we will include clinically randomized controlled trials that compare the effectiveness of acupuncture in combination with low-frequency repetitive transcranial magnetic stimulation to that of non-acupuncture in combination with low-frequency repetitive transcranial magnetic stimulation, which includes pharmacological and other non-pharmacological therapies.

(2) We will include randomized controlled trials (RCTs) published in either English or Chinese.

(3) Inclusion: adults (aged > 18 years) who meet the diagnostic criteria for insomnia, regardless of gender or race.

(4) Interventions: The experimental group receives acupuncture combined with low-frequency repetitive transcranial magnetic stimulation, while the control group receives non-acupuncture treatments combined with low-frequency repetitive transcranial magnetic stimulation. Both groups receive the same conventional treatment, and the treatment duration is not limited. The outcome indicators include polysomnography (PSG), Pittsburgh sleep quality index (PSQI), and clinical efficacy, with the PSGI being the required indicator. Exclusion criteria include reviews, basic research, conference papers, and those with inappropriate outcome indicators. It also includes not providing or partially missing outcome data, as well as obtaining relevant outcome data by contacting the original authors.

**Information sources** CNKI, Wanfang, PubMed, Embase, Vip, web of science, Cochrane Database and CBM Database.

**Main outcome(s)** SPQI.

**Additional outcome(s)** PSG, clinical efficacy.

**Quality assessment / Risk of bias analysis** Cochrane TOOL.

**Strategy of data synthesis** This study applied statistical analysis software (Review Manager 5.3 software) and STATA 16.0 software to perform a meta-analysis of the outcome data of the included studies. We used the odds ratio (OR) as a statistic to analyze the dichotomous variables, which allowed us to assess the effect and provide its 95% confidence interval (coanfid IC). We statistically analyzed continuous variables using the weighted mean difference (WMD) and 95% confidence intervals (C1). In this study, heterogeneity between studies was assessed and

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analyzed using the heterogeneity test; when heterogeneity between studies was low, i.e., homogeneous ( $P \geq 0.05$ ), meta-analysis was performed using the fixed effect model; when heterogeneity between studies was poor, i.e., heterogeneous ( $P < 0.05$ ), meta-analysis was performed using the random effect model. We used subgroup analysis (e.g., co-morbid depression and different courses of treatment) to further analyze the source of heterogeneity if there was significant heterogeneity among the study results, and we used sensitivity analyses to test the reliability of the results by aliasing out individual RCTs one by one.

**Subgroup analysis** We will conduct subgroup studies on factors such as diagnostic criteria, age group, duration of disorder, duration of treatment, and underlying treatment differences. We will also perform multiple regression analyses if necessary.

**Sensitivity analysis** The sensitivity analysis passed because, after deleting any of them, the combined results of the remaining literature did not significantly differ from what they would have been.

**Country(ies) involved** China.

**Keywords** acupuncture, Low-frequency transcranial magnetic stimulation, insomnia.

**Contributions of each author**

Author 1 - Ke weihao.

Author 2 - Chen Hongxin.