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The Efficacy and Safety of Acupuncture Treatment for Insomnia in Patients with Heart Failure A protocol for systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 July 2024 and was last updated on 25 July 2024.

INTRODUCTION

Review question / Objective The Efficacy and Safety of Acupuncture Treatment for Insomnia in Patients with Heart Failure.

Condition being studied With the acceleration of population aging and the improvement of medical standards, the survival period of patients with heart diseases has been prolonged, and the prevalence of heart failure continues to rise. Insomnia is a common comorbidity of heart failure. Traditional drug therapy and psychotherapy have certain limitations. Such as drug treatment may cause sleepiness, fatigue, other adverse reactions, drug resistance, and addiction. Psychological therapy has the disadvantages of different patient acceptance and individual differences in treatment effect and may need to be combined with drug therapy to treat insomnia more effectively.

Acupuncture treatment for insomnia has proven efficacy and can simultaneously improve the quality of life of heart failure patients. This protocol aims to evaluate the safety and effectiveness of acupuncture in treating insomnia in patients with heart failure.

METHODS

Participant or population Insomnia in Patients with Heart Failure.

Intervention The experimental group will include patients receiving conventional pharmacological treatment for heart failure combined with acupuncture therapy.

Comparator The control group will include patients receiving conventional pharmacological treatment for heart failure.

Study designs to be included Randomized controlled trials.

Eligibility criteria Patients meeting the diagnostic criteria for insomnia in heart failure, including the 2024 ACC Expert Consensus Decision Pathway for Treatment of Heart Failure With Reduced Ejection Fraction: A Report of the American College of Cardiology Solution Set Oversight Committee and The European Insomnia Guideline: An Update on the Diagnosis and Treatment of Insomnia 2023, without restrictions on age, gender, or region.

Information sources PubMed, Cochrane Library, EMBASE, China National Knowledge Infrastructure (CNKI), Wanfang Database, VIP Database, and Chinese Biomedical Literature Database.

Main outcome(s) These will be assessed through total sleep duration (hours), total wake time (minutes), wake after sleep onset (minutes), number of awakenings, sleep efficiency (%), total score on the Pittsburgh Sleep Quality Index (PSQI), total score on the Insomnia Severity Index (ISI), total score on the Sleep Quality Scale (SQS), quality of sleep score on the Morning Questionnaire (MQ), and sleep quality score from sleep diary.

Additional outcome(s) Quality of life scores on the SF-36, patients' clinical symptoms, and adverse events.

Quality assessment / Risk of bias analysis
Quality assessment: Assessment of Evidence Quality: We will use the GRADE approach to assess the quality of evidence. The quality of evidence will be classified into three levels: high, moderate, and low.
Risk of bias analysis: If ten or more studies are included, funnel plots and Egger's test will be used to evaluate reporting bias. We will carefully interpret the inspection results.

Strategy of data synthesis We will use REVMAN v5.4 software to analyze the selected literature data. We will use mean or standardized mean difference with 95% CIs for continuous data. We will assess heterogeneity using the Chi-squared test or I² test. When significant heterogeneity exists between studies ($P < 0.05$, $I^2 \geq 50\%$), we will use a random effects model; if heterogeneity is low, we will use a fixed effects model. When heterogeneity occurs, subgroup analysis or sensitivity analysis will be conducted to assess the sources of heterogeneity.

Subgroup analysis If significant heterogeneity exists, we will explore its sources through subgroup analysis. The following aspects will be considered: age, gender, intervention method, and insomnia severity. If data are insufficient, a qualitative synthesis analysis will be conducted by comparing the characteristics of the included studies.

Sensitivity analysis If sufficient data are available, we will perform sensitivity analysis to test the stability and reliability of the results, excluding certain low-quality or unblinded studies.

Country(ies) involved China.

Keywords acupuncture, heart failure, insomnia, meta-analysis, protocol.

Contributions of each author

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