INPLASY PROTOCOL

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Corresponding author:
Cheng Wang

519081091@qq.com

Author Affiliation:
Changchun University of Chinese MedicineChangchun University of Chinese Medicine.

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

Conflicts of interest:
None declared.

Safety and efficacy of acupuncture for anxiety and depression in patients with heart failure: a protocol for systematic review and meta-analysis

Wang, C[1]; Wang, J[2]; Shi, R[3]; Yu, KY[4]; Zhang, M[5]; Lu, RZ[6]; Shi, MP[7]; Deng,Y[8].

Review question / Objective: **P:anxiety and depression in heart failure patients; I: acupuncture or acupuncture combined with other treatment methods.C: non-acupuncture interventions, such as sham acupuncture, placebo, or other interventions. O: The primary outcome will be assessed by an anxiety or depression scale, such as the Hamilton Anxiety/ Depression Scale.Secondary outcomes will include improvement in patient symptoms and incidence of adverse events (AEs). S: We will collect published randomized controlled trials (RCTs) related to acupuncture for anxiety and depression in patients with heart failure, and there are no restrictions on language. These RCTs will be included, while non-RCTs, comments, Case report, cohort studies, cross-sectional studies, animal experiments, and reviews will be excluded.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 June 2022 and was last updated on 13 June 2022 (registration number INPLASY202260059).

INTRODUCTION

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acupuncture for anxiety and depression in patients with heart failure, and there are no restrictions on language.These RCTs will be included, while non-RCTs, comments, Case report, cohort studies, cross-sectional studies, animal experiments, and reviews will be excluded.

Condition being studied: In recent years, with the increase of patients with coronary heart disease, the number of patients with heart failure has also gradually increased. Coronary heart disease is one of the most common causes of heart failure. Anxiety and depression are frequent psychological disorders in patients with heart failure. Studies have shown that anxiety and depression can affect the quality of life of patients with heart failure, and can increase hospitalization and mortality. Conventional pharmacotherapy and psychotherapy have certain limitations. Acupuncture has therapeutic effects on heart disease and anxiety and depression, and has been widely used to relieve symptoms in patients with heart failure. This protocol aims to evaluate the safety and efficacy of acupuncture for anxiety and depression in patients with heart failure.

METHODS

Participant or population: All heart failure patients with anxiety and depression will be included in the study without any age, gender, region restrictions.

Intervention: The patients in the experimental group will receive the intervention of acupuncture or acupuncture combined with other treatment methods. There are many forms of acupuncture treatment, such as manual acupuncture, warm needling, scalp acupuncture, electroacupuncture, fire needling, auricular acupuncture, elongating needle, ormoxibustion.

Comparator: The patients in the control group will receive non-acupuncture interventions, such as sham acupuncture, placebo, or other interventions.The acupoint numbers, retaining time, and frequency will not be restricted in this protocol.

Study designs to be included: We will collect published randomized controlled trials (RCTs) related to acupuncture for anxiety and depression in patients with heart failure, and there are no restrictions on language.

Eligibility criteria: We will collect published randomized controlled trials (RCTs) related to acupuncture for anxiety and depression in patients with heart failure, and there are no restrictions on language.These RCTs will be included, while non-RCTs, comments, Case report, cohort studies, cross-sectional studies, animal experiments, and reviews will be excluded.

Information sources: We will search the following ten databases, including PubMed, web of science,Springer Cochrane Library, EMBASE, MEDLINE, WHO international clinical trials registry platform,China National Knowledge Infrastructure database (CNKI),Wan Fang database (Wan Fang),Chinese scientific journal database and Chinese Biomedical Literature Database. The databases will be searched from initiate to June 1, 2022 and the publishing language will be restricted to Chinese and English.

Main outcome(s): The primary outcome will be assessed by an anxiety or depression scale, such as the Hamilton Anxiety/ Depression Scale.

Additional outcome(s): Secondary outcomes will include improvement in patient symptoms and incidence of adverse events (AEs).

Quality assessment / Risk of bias analysis: Two reviewers will independently assess the risk of bias for each selected study using the Cochrane bias risk tool. They will be assessed in seven areas: random sequence generation, allocation concealment, blinding of participants and personnel, incomplete outcome data, blinding of outcome assessment, selective reporting, and other bias. All trials will be

divided into three levels: low risk of bias, high risk of bias and unclear bias.In the event of any disagreement between the two reviewers on the risk assessment and after discussion, consensus cannot be reached, the third reviewer will make the final decision.

Strategy of data synthesis: RevMan V.5.4 software will be used for data analysis and synthesis. We will analyze dichotomous data using Risk ratio with 95% CIs.For continuous data, a mean difference or a standard mean difference with 95% CIs will be applied for analysis.We will apply the x2 test or the I2 test to assess heterogeneity. When there was significant heterogeneity between studies ($P < .05$, $I2 \geq 50\%$), we performed a random effects model. If heterogeneity is low, a fixed effects model will be used.When heterogeneity occurs, subgroup analysis or sensitivity analysis will be performed to assess the source of heterogeneity.

Subgroup analysis: If there is significant heterogeneity, we will explore its source through subgroup analysis. The following aspects will be considered: age, gender, modality of intervention, and degree of depression. If the data is insufficient, the qualitative synthesis will be conducted.

Sensitivity analysis: If data are sufficient, we will perform a sensitivity analysis to test the robustness and reliability of the results, and certain low-quality or unblinded studies would be excluded.

Country(ies) involved: China.

Keywords: acupuncture heart failure; depression; anxiety; protocol; meta-analysis.

Contributions of each author:

Author 1 - Cheng Wang.
Email: 519081091@qq.com
Author 2 - Jia Wang.
Email: 1552625053@qq.com
Author 3 - Rui Shi.
Email: 4352637@qq.com
Author 4 - Keying Yu.
Email: 358036484@qq.com
Author 5 - Miao Zhang.
Email: zmiao0606@163.com
Author 6 - Ruozhu Lu.
Email: 532364820@qq.com
Author 7 - Mingpeng Shi.
Email: 422951302@qq.com
Author 8 - Yue Deng.
Email: dengyue@ccucm.edu.cn