

INPLASY PROTOCOL

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The authors have no conflicts of interest to disclose.

Comparison of efficacy and safety of complementary and alternative therapies for coronary heart disease complicated with anxiety or depression disorder A Bayesian network meta-analysis protocol

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Review question / Objective: **P:** (1) Patients diagnosed the CHD, including angina pectoris of stable and unstable, coexisting anxiety or depression disorder; (2) There are no age, gender, region or race restrictions. **I:** The experimental group was treated with complementary and alternative therapies including Chinese herbal medicine, acupuncture, massage, relaxation training, music therapy, cognitive-behavioral therapy, exercise therapies (yoga, Tai Chi, Five-Animal Frolics Exercise and so on) on the basis of treatment in the control group. All kinds of complementary and alternative therapies can be used alone or in any combination. **C:** The control group used basic treatment of anti-angina pectoris with or without anti-anxiety and depression western medicine. **O:** The frequency of acute attack angina, severity of angina pectoris; the change in the Hamilton Anxiety Rating scale (HAMA) score (with higher scores indicating more depression), Hamilton Depression Rating scale (HAMD) score, or Zung Self-Rating Anxiety Scale (SAS) score, Zung Self-Rating Depression Scale (SDS) score, or any other validated scales, which can assess severity of anxiety or depression are primary outcome measures. Secondary outcomes include total efficacy rate, electrocardiogram improvement, TCM symptoms score, changes of dosage of nitroglycerin and adverse effects. **S:** All RCTs and systematic reviews/meta-analysis relating to complementary and alternative therapies for patients suffering CHD complicated with anxiety or depression disorder will be screened out.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 February 2021 and was last updated on 16 February 2021 (registration number INPLASY202120046).

INTRODUCTION

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treated with complementary and alternative therapies including Chinese herbal medicine, acupuncture, massage, relaxation training, music therapy, cognitive-behavioral therapy, exercise therapies (yoga, Tai Chi, Five-Animal Frolics Exercise and so on) on the basis of treatment in the control group. All kinds of complementary and alternative therapies can be used alone or in any combination. C: The control group used basic treatment of anti-angina pectoris with or without anti-anxiety and depression western medicine. O: The frequency of acute attack angina, severity of angina pectoris; the change in the Hamilton Anxiety Rating scale (HAMA) score (with higher scores indicating more depression), Hamilton Depression Rating scale (HAMD) score, or Zung Self-Rating Anxiety Scale (SAS) score, Zung Self-Rating Depression Scale (SDS) score, or any other validated scales, which can assess severity of anxiety or depression are primary outcome measures. Secondary outcomes include total efficacy rate, electrocardiogram improvement, TCM symptoms score, changes of dosage of nitroglycerin and adverse effects. S: All RCTs and systematic reviews/meta-analysis relating to complementary and alternative therapies for patients suffering CHD complicated with anxiety or depression disorder will be screened out.

Condition being studied: With the acceleration of the pace of life, the phenomenon of anxiety and depression in patients with coronary heart disease (CHD) is more and more common, and “psychocardiology” arises spontaneously. At present, the drug treatments of psychocardiology are difficult to achieve satisfactory results, and the side effects are obvious. Complementary and replacement therapies of CHD complicated with anxiety or depression disorder play an increasingly positive role, but there is a lack of comparison among different complementary and alternative therapies. In this study, Bayesian network meta-analysis (NMA) analysis method will be used for the first time to synthesize all the evidences of direct and indirect comparison among a variety of

interventions, and rank their effectiveness and safety.

METHODS

Participant or population: (1) Patients diagnosed the CHD, including angina pectoris of stable and unstable, coexisting anxiety or depression disorder; (2) There are no age, gender, region or race restrictions.

Intervention: The experimental group was treated with complementary and alternative therapies including Chinese herbal medicine, acupuncture, massage, relaxation training, music therapy, cognitive-behavioral therapy, exercise therapies (yoga, Tai Chi, Five-Animal Frolics Exercise and so on) on the basis of treatment in the control group. All kinds of complementary and alternative therapies can be used alone or in any combination.

Comparator: The control group used basic treatment of anti-angina pectoris with or without anti-anxiety and depression western medicine.

Study designs to be included: All RCTs and systematic reviews/meta-analysis relating to complementary and alternative therapies for patients suffering CHD complicated with anxiety or depression disorder will be screened out.

Eligibility criteria: 1. Type of study All RCTs and systematic reviews/meta-analysis relating to complementary and alternative therapies for patients suffering CHD complicated with anxiety or depression disorder will be screened out. 2. Participants (1) Patients diagnosed the CHD, including angina pectoris of stable and unstable, coexisting anxiety or depression disorder; (2) There are no age, gender, region or race restrictions. 3. Interventions The control group used basic treatment of anti-angina pectoris with or without anti-anxiety and depression western medicine. The experimental group was treated with complementary and alternative therapies including Chinese herbal medicine, acupuncture, massage,

relaxation training, music therapy, cognitive-behavioral therapy, exercise therapies (yoga, Tai Chi, Five-Animal Frolics Exercise and so on) on the basis of treatment in the control group. All kinds of complementary and alternative therapies can be used alone or in any combination. 4. Outcome measures The frequency of acute attack angina, severity of angina pectoris; the change in the Hamilton Anxiety Rating scale (HAMA) score (with higher scores indicating more depression), Hamilton Depression Rating scale (HAMD) score, or Zung Self-Rating Anxiety Scale (SAS) score, Zung Self-Rating Depression Scale (SDS) score, or any other validated scales, which can assess severity of anxiety or depression are primary outcome measures. Secondary outcomes include total efficacy rate, electrocardiogram improvement, TCM symptoms score, changes of dosage of nitroglycerin and adverse effects.

Information sources: Our search from the beginning to January 2021 mainly by two researchers include English databases such as PubMed, EMBASE, Cochrane Library, Cochrane Central Register of Controlled Trials, Web of Science, et al and Chinese databases such as VIP full-text database, CNKI, Wanfang Database, including all RCTs of complementary and alternative therapies of CHD complicated with anxiety or depression disorder. Besides that, closely related ongoing RCTs in the ClinicalTrials.gov and World Health Organization International Clinical Trials Registration Platform (WHO ICTRP) will be searched. We will also track the references of searched systematic review or meta-analysis. If there is a disagreement in the process of literature screening, it can be discussed by two researchers and then decide whether to include it or not. If no agreement can be reached, it can be judged by the intervention of a third researcher. We will use the medical subject headings (MeSH) combined with free words to retrieve literature.

Main outcome(s): The frequency of acute attack angina, severity of angina pectoris; the change in the Hamilton Anxiety Rating scale (HAMA) score (with higher scores

indicating more depression), Hamilton Depression Rating scale (HAMD) score, or Zung Self-Rating Anxiety Scale (SAS) score, Zung Self-Rating Depression Scale (SDS) score, or any other validated scales, which can assess severity of anxiety or depression are primary outcome measures.

Additional outcome(s): Secondary outcomes include total efficacy rate, electrocardiogram improvement, TCM symptoms score, changes of dosage of nitroglycerin and adverse effects.

Quality assessment / Risk of bias analysis:

In this study, the Cochrane Collaboration's Risk of Bias Tool will be used to evaluate the bias risk of the included literature, which evaluates the bias risk of the literature from aspects of random method, assignment concealment, blind method, outcome data integrity, selective report, number of dropped cases, follow-up, and other biases. The three levels - low bias risk, unclear bias risk and high bias risk, will be used to evaluate each of the above aspect and finally the bias risk will be summarized.

Strategy of data synthesis:

Preliminary screening: through the same search pattern, two researchers independently exclude the literature obtained by reading literature titles and abstracts that does not meet the inclusion criteria, and collect the literature obtained after the initial screening. The coincident literature will be retained a copy to be included, and the disagreement literature will be discussed by the two researchers to decide whether to include it or not. If no agreement can be reached, the third party will intervene to judge. **Full-text screening:** download the full text of the qualified studies after preliminary screening, and the two researchers independently read and evaluate the full text of the same studies, and further establish whether the studies meet the inclusion criteria of this NMA. At the same time, the causes for literature exclusion are recorded. Like the preliminary screening, after the two researchers complete the literature independently, those with overlapping

views will be included, and those with different opinions will be discussed, and then if the results still are inconsistent, the third party can evaluate whether they are included or not. The following information of the literature will be extracted: ①General information: title, first author, country, year, journal, the support of the fund, the sources of the original literature; ②Methodological materials: randomization procedure, inclusion criteria, exclusion criteria, sample size, people lost to follow-up or dropped out, security, ethics; ③Research objects: age, race, gender, sources of participants, course of disease; ④Intervention measures and observation indicators: the methods of intervention, dosage, course of treatment, primary and secondary outcome measures, and follow-up time. If the information of the article is incomplete, the required information will be got through contacting the original author.

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Subgroup analysis: When there is heterogeneity among studies, the sources of heterogeneity will be explored and all the data will be divided into smaller units so that they can be compared in each subgroup.

Sensitivity analysis: Sensitivity analysis is an analytical method that determines the sensitivity of a study result or how some important factors change NMA. For example: using different statistical methods to re-analyze the data, such as using random effect model instead of fixed effect model; re-analyzing the data after reasonable estimation of the missing data; from the inclusion studies to exclude the literature with relatively poor quality and re-analysis, before and after comparison, whether there is a significant difference.

Country(ies) involved: China.

Keywords: coronary heart disease, anxiety, depression, Bayesian, network meta-analysis, complementary and alternative therapies, protocol.

Contributions of each author:

Author 1 - Xueyan Han.