# INPLASY PROTOCOL

To cite: Wang et al. Efficacy and safety of acupuncture combined with Chinese herbal medicine in the treatment of angina pectoris of coronary heart disease(CHD): a protocol for systematic review and meta analysis. Inplasy protocol 2021110100. doi: 10.37766/inplasy2021.11.0100

Received: 28 November 2021

Published: 28 November 2021

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Support: Without financial support.

Review Stage at time of this submission: Formal screening of search results against eligibility criteria.

Conflicts of interest: None declared.

## **INTRODUCTION**

Review question / Objective: This study is the protocol for a systematic review to evaluate the Efficacy and safety of acupuncture combined with Chinese herbal medicine in the treatment of angina

Efficacy and safety of acupuncture combined with Chinese herbal medicine in the treatment of angina pectoris of coronary heart disease(CHD): a protocol for systematic review and meta analysis

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Review question / Objective: This study is the protocol for a systematic review to evaluate the Efficacy and safety of acupuncture combined with Chinese herbal medicine in the treatment of angina pectoris of coronary heart disease: a systematic review and meta-analysis. we conducted a systematic review and meta-analysis of published randomized clinical trials (RCTs) of such combined therapy in the treatment of angina pectoris of coronary heart disease, It provides a reliable scientific basis for clinicians to use this approach to treat angina pectoris of coronary heart disease. Information sources: We conducted a systematic search for relevant documents in the Chinese and English databases, and the search time is limited to November 23, 2021. The following eight databases are included: PubMed,EMBASE, Web of Science, The Cochrane Library, Chinese Biomedical Literature Database (CBM), Chinese National Knowledge Infrastructure (CNKI), Chinese Science and Technology Periodical Database (VIP), Wanfang Database.Relevant journals were searched to trace the references included in the study. Other resources will be searched if necessary.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 November 2021 and was last updated on 02 December 2021 (registration number INPLASY2021110100).

pectoris of coronary heart disease: a systematic review and meta-analysis. we conducted a systematic review and meta-analysis of published randomized clinical trials (RCTs) of such combined therapy in the treatment of angina pectoris of coronary heart disease, It provides a

reliable scientific basis for clinicians to use this approach to treat angina pectoris of coronary heart disease.

Condition being studied: Coronary heart disease angina pectoris is a clinical syndrome in which episodic chest pain or chest discomfort is the main manifestation due to temporary ischemia and hypoxia of the myocardium due to coronary atherosclerosis and coronary artery functional changes (spasm). A large amount of clinical evidence confirms that acupuncture combined with Chinese herbal medicine in the treatment of coronary heart disease and angina pectoris can relieve the symptoms of angina pectoris and improve the performance of ECG ischemia; It still has obvious therapeutic effects in regulating the levels of cardiovascular regulatory peptides ET and cGRP. In order to better evaluate the effectiveness and safety of acupuncture combined with Chinese herbal medicine in the treatment of coronary heart disease and angina pectoris, we designed a systematic evaluation program to provide a reliable scientific basis for the future use of this method.

# **METHODS**

Search strategy: Search Pubmed database, Embase, Cochrane library, Chinese Biomedical Literature CD-ROM Database (CBMdisk), China Journal Network Full-text Database (CNKI), Wanfang Database, Web of Science (SCI-E), the retrieval time is established from each database Until October 2021, search for relevant eligible randomized controlled trials (RCT) with keywords or subject terms "acupuncture", "Chinese herbal medicine", and "coronary heart disease angina". Outcome indicators were clinical symptoms of coronary heart disease and angina pectoris, changes in electrocardiogram, changes in blood lipids, and significant improvement in TCM syndromes before and after. Two researchers independently carry out data extraction and quality assessment, and use RevMan5.3 software to carry out final data analysis and assessment.

Participant or population: For patients who meet the clinical diagnostic criteria for coronary heart disease and angina pectoris, there are no restrictions on age, gender, course of disease, and geographic differences.

Intervention: The experimental group received acupuncture (including acupuncture, warm acupuncture and other treatment methods) combined with Chinese herbal treatment, while the control group received conventional treatment for coronary heart disease and angina pectoris.

Comparator: While the control group received conventional treatment for coronary heart disease and angina pectoris.

Study designs to be included: The only randomized controlled trial was included. Non-randomized controlled trials and uncontrolled clinical trials will be excluded. Whether single-blind, double-blind, or unblinded.

Eligibility criteria: Evidence from the International Evidence-based Medicine / Cochrane Collaboration Volume design :(1) randomized controlled trials were used in this study Trial, RCT), with or without assignment hiding and blinding; (2)The control group received conventional western medicine treatment, The treatment group took basal This treatment plus acupuncture combined with Chinese herbal medicine Basic treatment includes anticoagulation, antiplatelet aggregation, β-receptor blockers, nitrates, angiotensin converting enzyme inhibitor (ACEI), statins regulating blood lipids and other drugs; (3) conform to the public Recognized and authoritative diagnostic criteria for angina pectoris of coronary heart disease. Exclusion criteria (1) Do not meet or have no diagnostic criteria; (2) No According to the group, or the test design is flawed, or the statistical method is improper; (3) Not available Literature on outcome indicators; (4) Animal experiment, review, experience summary, case report, Case review and retrospective study.

Information sources: We conducted a systematic search for relevant documents in the Chinese and English databases, and the search time is limited to November 23, 2021. The following eight databases are included: PubMed, EMBASE, Web of Science, The Cochrane Library, Chinese Biomedical Literature Database (CBM), Chinese National Knowledge Infrastructure (CNKI), Chinese Science and Technology Periodical Database (VIP), Wanfang Database.Relevant journals were searched to trace the references included in the study. Other resources will be searched if necessary.

Main outcome(s): Coronary heart disease angina pectoris clinical symptoms, angina pectoris duration, attack frequency, electrocardiogram performance, triglycerides, cholesterol indicators, TCM syndrome scores.

Data management: Data extraction was conducted independently by 2 reviewers in accordance with the preset standardized data extraction form. If there is any disagreement or doubt, the decision should be made after discussion or third party opinion should be consulted. The extracted information includes the following contents: the basic information included in the study, such as the research title, first author, published journal, etc; baseline characteristics of the study subjects and intervention measures; the key elements of bias risk assessment; outcome indicators and outcome measurement data concerned.

### Quality assessment / Risk of bias analysis:

Two searchers searched the literature independently and checked one by one Include the study. If there is disagreement about the inclusion of the study, consult the expert to decide Decide whether to include it and try to avoid missed detection. Cochrane systems reviewers were used Volume 5.1 Bias risk Assessment tool, the included literature was qualifies from the following six aspects Quantitative evaluation:(1) whether random sequence generation is sufficient;(2) Whether the allocation is hidden; (3) Whether blind

method is used;(4) Whether the result data is complete;(5) Selective reporting; (6) Whether there is publication bias.

Strategy of data synthesis: Two authors will independently appraise the methodological quality of each trial in six dimensions: selection bias, performance bias, detection bias, attrition bias, reporting, and other biases. Any disagreements will be resolved through discussions between the two authors or consultation with a third researcher. Articles not made available with complete clinical data will be excluded after several attempts have been made to contact the authors of those studies.

Subgroup analysis: As potential heterogeneity is inevitable, in order to reduce the impact of the final result, We performed subgroup analysis of all information collected in this study based on age, disease course, treatment type, treatment duration of all included subjects, and treatment of the control group.

Sensitivity analysis: Considering the impact of sensitivity analysis on methodological quality, we will test the robustness of the results by excluding low-quality and high-bias risks.

Country(ies) involved: China.

Keywords: acupuncture, Chinese herbal medicine, angina pectoris of coronary heart disease, systematic review, meta-analysis.

### **Contributions of each author:**

Author 1 - Shuang Wang.

**Author 2 - Aidong Liu.** 

Author 3 - Zhilei Wang.

Author 4 - Yue Zhang.