# INPLASY PROTOCOL

**Corresponding author:**
**Guoqi Dong**

**2230443055@qq.com**

**Author Affiliation:**
**Nanjing University of Chinese Medicine**

**Support:** None

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

**Conflicts of interest:** None.

## Network meta-analysis of Traditional Chinese medicines for depression in coronary heart disease patients

Dong, GQ[1]; Lu, MY[2]; Zhang, HR[3]; Chen, H[4]; Wu, XL[5]; Gu, YH[6].

**Review question / Objective:** We aim to evaluate the therapeutic efficacy of Traditional Chinese medicine treatment (Chinese medicine decoction, Chinese medicine injection, Chinese medicine compound preparation, acupuncture, moxibustion etc.) in the treatment of depression in coronary heart disease.

**Condition being studied:** Patients with CVD (cardiovascular diseases) typically have other health issues, including mental health problems. A prospective, longitudinal cohort showed that 61.7% of patients with CVD demonstrated symptoms of depression, anxiety. Besides depression and other mental illnesses have been identified as major risk factors for CVD. In 1918, Heinmth put forward the concept of psychosomatic diseases. Professor Dayi Hu proposed the concept of Psychocardiology first, and he pointed out that in the treatment of patients with coronary heart disease, we should pay attention to the mental state of patients. Under the guidance of Traditional Chinese Medicine, Chinese medicine decoction, Chinese patent medicine and other internal treatment methods, as well as acupuncture, acupoint sticking and other external treatment methods, have made great progress in the treatment of depression in CVD. However, which method can better treat the disease has not been studied. So far, there is no meta-analysis on the efficacy of different TCM therapies in the treatment of depression in CVD. Present network meta-analysis will systematically collect RCTs and quasi-Rcts that compared different TCM therapies to compare the differences between all TCM therapies in depression in CVD, and to assess the comparative effectiveness of TCM therapies.

## INTRODUCTION

**Review question / Objective:** We aim to evaluate the therapeutic efficacy of Traditional Chinese medicine treatment (Chinese medicine decoction, Chinese medicine injection, Chinese medicine compound preparation, acupuncture, moxibustion etc.) in the

treatment of depression in coronary heart disease.

**Condition being studied:** Patients with CVD (cardiovascular diseases) typically have other health issues, including mental health problems. A prospective, longitudinal cohort showed that 61.7% of patients with CVD demonstrated symptoms of depression, anxiety. Besides depression and other mental illnesses have been identified as major risk factors for CVD. In 1918, Heinmth put forward the concept of psychosomatic diseases. Professor Dayi Hu proposed the concept of Psychocardiology first, and he pointed out that in the treatment of patients with coronary heart disease, we should pay attention to the mental state of patients. Under the guidance of Traditional Chinese Medicine, Chinese medicine decoction, Chinese patent medicine and other internal treatment methods, as well as acupuncture, acupoint sticking and other external treatment methods, have made great progress in the treatment of depression in CVD. However, which method can better treat the disease has not been studied. So far, there is no meta-analysis on the efficacy of different TCM therapies in the treatment of depression in CVD. Present network meta-analysis will systematically collect RCTs and quasi-Rcts that compared different TCM therapies to compare the differences between all TCM therapies in depression in CVD, and to assess the comparative effectiveness of TCM therapies.

## METHODS

**Participant or population:** Patients diagnosed with CVD complicated with depression.

**Intervention:** Chinese medicine treatment (Chinese medicine decoction, Chinese medicine injection, Chinese medicine compound preparation, acupuncture, moxibustion etc).

**Comparator:** Western medicine, other traditional Chinese medicine or placebo.

**Study designs to be included:** We include randomized controlled trials (RCTs) or quasi-randomized controlled trial. Observational, cohort, case-control, case series will be excluded.

**Eligibility criteria:** Inclusion criteria: (1)The study was conducted as randomized controlled trials (RCTs) or quasi-randomized controlled trial (2)Patients diagnosed with CHD complicated with depression. (3)Intervention involve Chinese medicine treatment, such as: Chinese medicine decoction, Chinese medicine injection, Chinese medicine compound preparation, acupuncture, moxibustion etc Exclusion criteria: (1)Repeated literature (2)Observational, cohort, case-control, case series (3)Literature that do not have index to evaluate the severity of depression (4)Postoperative patients (5)Literature lacking important data and cannot be obtained after communication with the author.

**Information sources:** We searched the following electronic bibliographic databases for Chinese literature:CNKI(China National Knowledge Infrastructure), Wanfang Data (Wanfang science and technology information database), VIP (China Weipu science and technology journal database), CBM (Chinese biomedical literature database). And we searched following electronic bibliographic databases for English literature: The Cochrane Library, PubMed, Embase, Web of Science. Language is limited to Chinese or English, the search date will be up to April 20, 2019.

**Main outcome(s):** The measurements included the Twenty-four item Hamilton Rating Scale for Depression (HAMD-24) and Self-Rating Depression Scale (SDS).

**Data management:** All citations will be improted into Endnote X9 to manage citations from all database and remove duplicate citations. Initially, two authors will independently screen the titles and abstracts for primary eligibility. Subsequently, two authors will assess

articles for inclusion by reading the full texts. All disagreement will be settled by disscussion with a third author Data extraction and management: Data extraction will be performed by two authors independently according a prespecified data extraction form and A third author will validate data. The following data will be extracted: study characteristics(including information of authors, year of publication, sample size of study, region, study design,treatment and control etc), population characteristics (age, gender, baseline score of HAMD or SDS) and reported outcomes (change scores HAMD or SDS after completion).

**Quality assessment / Risk of bias analysis:** The methodological quality of all RCTs and quasi-RCT was evaluated indepentently by two authors and disagreement will be resolved by either discussion or the third-author resolution. Risk of bias was assessed with 'risk of bias' tool of Cochrane Handbook for Systematic Review of Interventions on following relevant domains: ①random sequence generation, ②allocation concealment, ③blinding of participants and personnel, ④blinding of outcome assessment, ⑤incomplete outcome data, ⑥selective reporting and ⑦other biases. The risk of bias will be determined for each domain will be defined as low, medium and high.

**Strategy of data synthesis:** To pool the results, pairwise meta-analysis will be performed by a random-effect model after combining similar studies. The $\chi^2$ test and $I^2$-statistic will be calculated for heterogeneity. If $I^2$ value greater than 50%, significant heterogeneity can be considered. If it is possible, different NMAs will be considered for different treatment. Publication bias will be also assessed in our study. The analysis will be peformed by R and Stata.

**Subgroup analysis:** If the data is sufficient and reliable, subgroup analysis shall be conducted with variable consideration.

**Sensibility analysis:** Sensitivity analysis will be performed to investigate sources of heterogeneity to determine the robustness and reliability of pooled outcome results.

**Country(ies) involved:** China.

**Keywords:** Coronary heart disease; Depression; Traditional Chinese Medicine; Network Meta-Analysis.

**Contributions of each author:**
Author 1 - Guoqi Dong.
Author 2 - Mengye Lu.
Author 3 - Xiaoliang Wu.
Author 4 - Hao Chen.
Author 5 - Hongru Zhang.
Author 6 - Yihuang Gu.