

INPLASY PROTOCOL

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Corresponding author:
Yong Jiang

jiangyong@pyztc.com

Author Affiliation:
Chengdu University of
Traditional Chinese Medicine,
School of Basic Medical
Sciences

Support: Xinglin scholars No:
030041044.

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The authors have no conflict of
interests to disclose.

Warming yang method in traditional Chinese medicine for depression: A protocol for systematic review and meta-analysis

Deng, J¹; Wang, C²; Jiang, Y³.

Review question / Objective: The study is aim to evaluate the efficacy and safety of warming yang method in traditional Chinese medicine for depression.

Condition being studied: Depression is a chronic psychological disease with genetic tendency caused by a variety of factors, the main symptoms are low emotion, interest, cognition, thinking and disorder of physiological function, even numbness, or hallucination, delusion and other psychotic symptoms. Some patients had suicide, or accompanied by obvious anxiety and (or) provocation, and even aggressive behavior. The pathogenesis of this disease is still unclear, the main point of view is the following aspects: 5-HT, dopamine, norepinephrine, Functional changes of hypothalamus pituitary adrenal axis in patients with depression, genetic. Although 5-HT and NE antidepressants have good antidepressant effect, there are still adverse reactions of different severity, and patients' compliance is low. Human beings are a complex creature, and depression has many pathogenic factors, so we must take a holistic approach to treat it. This is fully a close correspondence with the characteristics of TCM syndrome differentiation. Many single medicine and decoctions have been proved effective on depression from pharmacological aspects, not only in clinical observation.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 November 2020 and was last updated on 28 November 2020 (registration number INPLASY2020110129).

INTRODUCTION

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warming yang method in traditional Chinese medicine for depression.

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METHODS

Participant or population: All patients diagnosed with depression will be included and there are no restrictions on their nationality, occupation, educational background, belief, age, body or race.

Intervention: Warming yang method in traditional Chinese medicine.

Comparator: The comparisons will be either with other therapeutic agents or placebo.

Study designs to be included: Randomized controlled trials (RCTs) will be included.

Eligibility criteria: Types of studies. Randomized controlled trials (RCTs) in Chinese and English will be enrolled in this system review. We will exclude non-randomized controlled trials (non-RCTs), quasirandomized controlled trials (qRCTs),

reviews, experimental studies, case reports, cohort studies, expert experience, duplicate publication and the included study that the data is incomplete or missing. Types of participants. There are no restrictions on participants with depression. Patient and public involvement. This study has no patient and public involvement in consideration of this protocol for a systematic review Types of interventions. Warming yang method in Chinese medicine will be included. The comparisons will be either with other therapeutic agents or placebo.

Information sources: We will retrieve the following databases: PubMed, the Cochrane Library, Chinese Science and Technique Journals Database (VIP), Chinese Biomedical Literature Database (CB), Excerpt Medica Database (EMBASE), MEDLINE, Chinese National Knowledge Infrastructure Database (CNKI), and the Wanfang Database. We will search all the above databases from the available date of inception to November 2020.

Main outcome(s): 1. The reduction ratio of Hamilton Depression Rating Scale (HAMD-17) 2. security index.

Quality assessment / Risk of bias analysis: 2 authors (JD and CW) will use the Cochrane tool of risk of bias to assess the risk of bias independently. The disagreement will be settled by another reviewer (YJ). We will access the following contents: selection bias (random sequence generation, and allocation concealment), performance bias (blinding of participants and personnel), detection bias (blinding of outcome assessment), attrition bias (incomplete outcome data), reporting bias (selective outcome reporting), and other bias (other sources of bias). Studies will be evaluated high, low and unknown.

Strategy of data synthesis: The meta-analysis in this review will use RevMan 5.3 software. Continuous variables will be reported as mean difference with 95% confidence intervals (CIs). For different measurement scales, we will use the standardized mean difference analysis with

95% CIs. Categorical variables will be summarized as risk ratios or odds ratio with 95% CIs. All analyses will be conducted in accordance with the Cochrane Handbook for Systematic Reviews of Interventions. Heterogeneity will be assessed by visual inspection of the forest and tested by standard Chi-squared statistic and a significance level of 0.1. Furthermore, the I² statistic will be used to examine heterogeneity to quantify inconsistency. Fixed or random effects models will be performed in meta-analysis. If I²>0.5, the random effects models will be used.

Subgroup analysis: If heterogeneity is detected, subgroup analysis will be performed to explore the differences in the methodologic quality, age, race/ethnicity, and types of Chinese medicine.

Sensitivity analysis: Sensitivity analysis will be performed to examine the robustness of the result if there are sufficient studies included. The factors on effect are as follows: methodologic quality: analysis will be performed excluding studies of poor methodologic quality sample size: analysis will be performed excluding small sample size studies diagnostic criteria: analysis will be performed in studies of the same diagnostic criteria.

Country(ies) involved: China.

Keywords: depression, traditional Chinese medicine, Warming yang method, protocol, meta-analysis.

Contributions of each author:

Author 1 - Jiashuai Deng - Conceptualization, data curation, formal analysis, methodology, project administration, writing-original draft, writing-review & editing.

Email: jasondeng15@outlook.com

Author 2 - Changhong Wang - Conceptualization, methodology, project administration, writing-original draft.

Email: 7416795392@qq.com

Author 3 - Yong Jiang - Conceptualization, supervision, writing review & editing.

Email: jiangyong@pyztc.com