INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Effecacy and Safty of Moxibustion for Depression and Anxiety in COVID-19: A protocol for systematic review and meta-analysis

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Review question / Objective: **The research aims to observe the effecacy and safty of moxibustion for anxiety and depression in COVID-19.**
Condition being studied: **Coronavirus disease 2019 (COVID-19) is an acute respiratory infectious disease that makes breathing difficult and is often accompanied by anxiety and depression. Moxibustion, a special external treatment of traditional Chinese medicine, has shown beneficial effects in the treatment of anxiety and depression.**
Information sources: **The Cochrane Central of Controlled Trials (CENTRAL), PubMed, Embase, Chinese Biomedical Literature Database, CNKI, Weipu Chinese Science and Technology Journal Database, Wanfang Database, and related journals.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 May 2022 and was last updated on 29 May 2022 (registration number INPLASY202250162).

INTRODUCTION

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beneficial effects in the treatment of anxiety and depression.

METHODS

Search strategy: The Cochrane Central of Controlled Trials (CENTRAL), PubMed, Embase, Chinese Biomedical Literature Database, CNKI, Weipu Chinese Science and Technology Journal Database, Wanfang Database, and related journals will be searched. The search time will be from the establishment of the database-2022.05.31. Randomized clinical trials and retrospective cohort studies will be included.

Participant or population: Patients with anxiety and depression in COVID-19.

Intervention: The intervention measures in the experimental group should contain moxibustion.

Comparator: As included in eligible randomized clinical trials and retrospective cohort studies.

Study designs to be included: Randomized clinical trials and retrospective cohort studies will be included.

Eligibility criteria: PICOS principles will be consulted to establish the inclusion and exclusion criteria of this systematic review.

Information sources: The Cochrane Central of Controlled Trials (CENTRAL), PubMed, Embase, Chinese Biomedical Literature Database, CNKI, Weipu Chinese Science and Technology Journal Database, Wanfang Database, and related journals.

Main outcome(s): Effectiveness indicators.Clinical variables will be set as the effectiveness indicators, such as mental anxiety factor score somatic anxiety factor score, and quality of life.

Additional outcome(s): The adverse reactions are continuous variables.

Data management: Two researchers will use standardized tables to independently extract data in duplicate from all eligible trials according to the inclusion and exclusion criteria mentioned above. In case of disagreement, they will agree through discussion, or submit the issue to a third party for evaluation. Before the screening process, the third party will use a standardized screening form, and will perform calibration exercises. Two evaluators will independently extract data according to the pre-designed extraction table, and the extracted content will include:

1. Basic information: research number, title and author of the literature, publication time, source of the literature.
2. Research objects: patient age, gender, number of trials in each group, trial time, and baseline comparability.
3. Intervention measures: different intervention measures adopted by the experimental group and the control group.
4. Research results: the result indicators needed for this systematic review, and other indicators mentioned in the article that are not needed in this systematic review.

Quality assessment / Risk of bias analysis: The methodological quality of each included study will be assessed independently by two reviewers using two tools. The Cochrane collaboration tool will be used to assess the quality of randomized controlled trials. It comprises the following 7 aspects: random sequence generation, allocation concealment, blind method, incomplete result data, selective reporting, and other biases. The quality assessment results of each item can be divided into three grades: “low risk”, “high risk” and “unclear”. The more rigorous the design and the higher the methodological quality of each RCT, the lower the risk coefficient. The Newcastle Ottawa Scale (NOS) will be used to assess the quality of retrospective studies. This method includes three aspects to the evaluation: the selection method, comparability and contact exposure assessment method of case group and control group. The higher the score, the higher the quality of the study. When necessary, the consensus on

this issue will be studied with the help of a third party.

Strategy of data synthesis: The RevMan5.3 software provided by the Cochrane website will be used for the analysis. Categorical variables will be expressed by odds ratio (OR) and marked with 95% confidence interval (CI). Continuous variables will be expressed by mean difference (MD) and marked with 95% CI. If P0.1 or I^2<50%, it means that the heterogeneity between groups is small, and the fixed effect model will, in this case, be used for combined analysis; when P50%, it shows that the heterogeneity between the groups is large, and the random effects model will then be used for combined analysis, and the results shown in forest plots. Analysis of potential publication bias will be shown in a funnel chart, and sensitivity analysis and subgroup analysis will be used when necessary.

Subgroup analysis: Subgroup analysis will be used to evaluate the therapeutic effects among different drugs. Inverted funnel plots and Egger's regression test will be used to determine publication bias when the number of included studies exceeds 10 in the network meta-analysis.

Sensitivity analysis: We carried out a sensitivity analysis to investigate the robustness of the conclusions. The principal decision nodes include the method quality, sample size, and impact of missing data. Therefore, the impact of low-quality research on overall results was assessed.

Country(ies) involved: China.

Keywords: moxibustion, anxiety and depression, protocol, effecacy and safty, coronavirus disease 2019.

Contributions of each author:

Author 1 - Wenyan Yu - Author 1 drafted the manuscript.
Email: 674880418@qq.com
Author 2 - Xuhao Li - The author provided statistical expertise.
Author 3 - Yunliang Zhang - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.
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