INPLASY PROTOCOL

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Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
None declared.

Quality of evidence supporting the role of chinese herbal medicine for the treatment of post-stroke depression: A protocol for an overview of systematic review and meta-analysis

Shi, HS[1]; Dong, CD[2]; Liu, WB[3]; Peng, M[4]; Si, GM[5]; Sun, FS[6].

Review question / Objective: **The inclusion criteria were as follows: (a) study design: SRs/MAs based on randomized controlled trials (RCTs); (b) participants: the participants had PSD diagnosed according to any authoritative diagnostic criteria, no restrictions on sex, age, race, onset time, or the source of cases; (c) intervention: CHM therapy (The forms of CHM including purification for injection, decoction, patent drug, preparation, et al) versus conventional PSD drugs or CHM therapy combined with conventional PSD drugs versus conventional PSD drugs alone; and (d) outcomes: effective rate, Hamilton Depression Rating Scale (HAMD), NIH Stroke Scale(NIHSS), Barthel Index (BI), Scandinavian Stroke Scale (SSS), Treatment Emergent Symptom Scale (TESS), Neurological Function Defect Scale (NFDS), severity of neurological impairment scores and potential gastrointestinal and neurological adverse events.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 January 2022 and was last updated on 03 January 2022 (registration number INPLASY202210001).

INTRODUCTION

Review question / Objective: **The inclusion criteria were as follows: (a) study design: SRs/MAs based on randomized controlled trials (RCTs); (b) participants: the participants had PSD diagnosed according to any authoritative diagnostic criteria, no restrictions on sex, age, race, onset time, or the source of cases; (c) intervention: CHM therapy (The forms of CHM including purification for injection, decoction, patent drug, preparation, et al) versus conventional PSD drugs or CHM therapy combined with conventional PSD drugs versus conventional PSD drugs alone; and (d) outcomes: effective rate, Hamilton Depression Rating Scale (HAMD), NIH**

Stroke Scale(NIHSS), Barthel Index (BI), Scandinavian Stroke Scale (SSS), Treatment Emergent Symptom Scale (TESS), Neurological Function Defect Scale (NFDS), severity of neurological impairment scores and potential gastrointestinal and neurological adverse events.

Condition being studied: Numerous PSD patients are contraindicated to antidepressants, so it is of great clinical value to develop an effective and safe PSD replacement therapy to supplement and replace existing antidepressant-centered treatment strategies. As one of the modalities of complementary and alternative medicine, Chinese herbal medicine (CHM) has certain therapeutic effect on PSD because of its multi-target multi-compound nature that potentially benefits neurological function, rehabilitation outcome, quality of life, and depressive symptoms [[[] Pelkonen O, Xu Q, Fan TP. Why is Research on Herbal Medicinal Products Important and How Can We Improve Its Quality? J Tradit Complement Med. 2014 Jan;4(1):1-7. doi: 10.4103/2225-4110.124323. PMID: 24872927; PMCID: PMC4032837.]]. Meta-analyses (MAs)/ Systematic reviews (SRs) are thought to be the reliable criteria for evaluating the effectiveness of therapeutic interventions, but their methods must strictly adhere to a set of guidelines to minimize the bias in answering specific research questions [[[] Higgins, J. P., Thomas, J., Chandler, J., Cumpston, M., Li, T., Page, M. J., & Welch, V. A. (Eds.). (2019). Cochrane handbook for systematic reviews of interventions. John Wiley & Sons.]]. Nevertheless, a large proportion of SRs/ MAs authors do not strictly adhere to the criteria above, which may leads to low-quality reviews and difficulty in providing convincing results and conclusions. We obtained a number of published systematic reviews (SRs)/ meta-analyses (MAs) that reported the effectiveness of CHM on PSD by searching several necessary databases, but their methodological and quality of evidence has not been evaluated. Therefore, we designed and composed an overview to summarize the evidence on the safety and effectiveness of CHM for PSD.

METHODS

Participant or population: The participants had PSD diagnosed according to any authoritative diagnostic criteria, no restrictions on sex, age, race, onset time, or the source of cases.

Intervention: CHM.

Comparator: CHM therapy (The forms of CHM including purification for injection, decoction, patent drug, preparation, et al) versus conventional PSD drugs or CHM therapy combined with conventional PSD drugs versus conventional PSD drugs alone.

Study designs to be included: Study design: SRs/MAs based on randomized controlled trials (RCTs).

Eligibility criteria: (a) study design: SRs/ MAs based on randomized controlled trials (RCTs); (b) participants: the participants had PSD diagnosed according to any authoritative diagnostic criteria, no restrictions on sex, age, race, onset time, or the source of cases; (c) intervention: CHM therapy (The forms of CHM including purification for injection, decoction, patent drug, preparation, et al) versus conventional PSD drugs or CHM therapy combined with conventional PSD drugs versus conventional PSD drugs alone; and (d) outcomes: effective rate, Hamilton Depression Rating Scale (HAMD), NIH Stroke Scale(NIHSS), Barthel Index (BI), Scandinavian Stroke Scale (SSS), Treatment Emergent Symptom Scale (TESS), Neurological Function Defect Scale (NFDS), severity of neurological impairment scores and potential gastrointestinal and neurological adverse events.

Information sources: Cochrane Library, PubMed, Web of Science, EMBASE, China National Knowledge Infrastructure (CNKI), Wanfang Database, SinoMed, Chongqing VIP.

Main outcome(s): Effective rate, Hamilton Depression Rating Scale (HAMD), NIH Stroke Scale(NIHSS), Barthel Index (BI),

Scandinavian Stroke Scale (SSS), Treatment Emergent Symptom Scale (TESS), Neurological Function Defect Scale (NFDS), severity of neurological impairment scores and potential gastrointestinal and neurological adverse events.

Quality assessment / Risk of bias analysis: Assessment of Methodological Quality The Assessment System for Evaluating Methodological Quality 2 (AMSTAR-2) [23] scale was used to assess the methodological quality of the included SRs/MAs. It consists of 16 items, 7 of which are critical areas (2、4、7、9、11、13, and 15). Each item is assessed using three assessment options, yes, partially yes, or no. Assessment of Risk of Bias The risk of bias of the included SRs/MAs is assessed by the ROBIS scale [24]. The scale is completed in 3 stages to assess the overall risk of bias. The results are judged as "low", "unclear", or “high". Assessment of Reporting Quality The list of PRISMA is used to assess the quality of each SR/MA report based on the following areas: (a) title, (b) summary, (c) introduction, (d) method, (e) result, (f) Discussion, (g) funding. It consists of 27 projects, with a focus on reporting methods and results in a meta-analysis. Based on the completeness of the project information report, each project is considered "yes" (full report), "partial yes" (partial report) or "no" (no report). Assessment of Quality of Evidence The GRADE scale is used to assess the quality of the evidence of the included SRs/MAs, downgrading from five aspects: research limitations, inconsistencies, indirectness, imprecision, and publication bias [25].

Strategy of data synthesis: Assessment of Methodological Quality - The Assessment System for Evaluating Methodological Quality 2 (AMSTAR-2) [23] scale was used to assess the methodological quality of the included SRs/MAs. It consists of 16 items, 7 of which are critical areas (2、4、7、9、11、13, and 15). Each item is assessed using three assessment options, yes, partially yes, or no. Assessment of Risk of Bias - The risk of bias of the included SRs/MAs is assessed by the ROBIS scale [24]. The scale is completed in 3 stages to assess the overall risk of bias. The results are judged as "low", "unclear", or “high". Assessment of Reporting Quality - The list of PRISMA is used to assess the quality of each SR/MA report based on the following areas: (a) title, (b) summary, (c) introduction, (d) method, (e) result, (f) Discussion, (g) funding. It consists of 27 projects, with a focus on reporting methods and results in a meta-analysis. Based on the completeness of the project information report, each project is considered "yes" (full report), "partial yes" (partial report) or "no" (no report). Assessment of Quality of Evidence - The GRADE scale is used to assess the quality of the evidence of the included SRs/MAs, downgrading from five aspects: research limitations, inconsistencies, indirectness, imprecision, and publication bias [25].###Assessment of Methodological Quality - The Assessment System for Evaluating Methodological Quality 2 (AMSTAR-2) [[[] Shea BJ, Reeves BC, Wells G, et al. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. BMJ. 2017;358:j4008. Published 2017 Sep 21. doi:10.1136/bmj.j4008]] scale was used to assess the methodological quality of the included SRs/MAs. It consists of 16 items, 7 of which are critical areas (2、4、7、9、11、13, and 15). Each item is assessed using three assessment options, yes, partially yes, or no. ###Assessment of Risk of Bias - The risk of bias of the included SRs/MAs is assessed by the the risk of bias in systematic (ROBIS) [[[] Whiting P, Savović J, Higgins JP, et al. ROBIS: A new tool to assess risk of bias in systematic reviews was developed. J Clin Epidemiol. 2016;69:225-234. doi:10.1016/j.jclinepi.2015.06.005]] scale. The scale was completed in 3 stages to assess the overall risk of bias. The results are judged as "low", "unclear", or “high". ###Assessment of Reporting Quality - The list of The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [[[] Moher D, Liberati A, Tetzlaff J, Altman DG;

PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. BMJ. 2009;339:b2535. Published 2009 Jul 21. doi:10.1136/bmj.b2535]] was used to assess the quality of each SR/MA report based on the following areas: (a) title, (b) summary, (c) introduction, (d) method, (e) result, (f) Discussion, (g) funding. It consists of 27 projects, with a focus on reporting methods and results in a meta-analysis. Based on the completeness of the project information report, each project is considered "yes" (full report), "partial yes" (partial report) or "no" (no report). ###Assessment of Quality of Evidence - The Grading of Recommendations, Assessment, Development and Evaluation.

Subgroup analysis: No.

Sensitivity analysis: No.

Country(ies) involved: China.

Keywords: Chinese herbal medicine, Poststroke depression, systematic reviews, and meta-analysis.

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