INPLASY PROTOCOL

Efficacy and safety of massage in the treatment of post-stroke depression: a systematic review and meta-analysis of protocols

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Review question / Objective: In this study, we conducted a comprehensive literature search to further systematically evaluate the clinical efficacy and safety of massage in the treatment of depression after stroke, providing the latest evidence-based medicine for the clinical treatment of depression after stroke.

Condition being studied: Stroke is an acute cerebrovascular disease. Depression is a common complication of stroke. Depression after a stroke, if left untreated, may not only lead to a recurrence of the stroke, but also may cause anxiety, insomnia, cognitive decline and other mental disorders. At present, the treatment method for post-stroke depression is mainly drug therapy. A meta-analysis involving 52 studies showed that SSRI drugs can significantly reduce the disability rate and neurological deficits of patients when treating depression after stroke and improving the mood of patients. It can be seen that drug treatment has an important position. But we should also see the side effects and risks of drug treatment, and economic consumption. Studies have shown that the use of SSRI drugs increases the risk of bleeding complications and makes the elderly more likely to fall. There are also epidemiological studies that show that SSRI is also indispensable to patients' subsequent strokes. we should find a safer, cheaper, and effective treatment intervention for patients with post-stroke depression. According to research, massage can effectively improve mood, create a feeling of pleasure, and reduce the occurrence of major adverse events in stroke patients.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 November 2020 and was last updated on 20 November 2020 (registration number INPLASY2020110085).

INTRODUCTION

Review question / Objective: In this study, we conducted a comprehensive literature search to further systematically evaluate the clinical efficacy and safety of massage in the treatment of depression after stroke, providing the latest evidence-based medicine for the clinical treatment of depression after stroke.

Rationale: Depression is a common complication of stroke. Depression after a stroke, if left untreated, may not only lead to a recurrence of the stroke, but also may cause anxiety, insomnia, cognitive decline and other mental disorders. Some studies have shown that massage can effectively improve the symptoms of depression in patients after stroke. To our knowledge, there is no systematic review of whether massage therapy is safe and effective in treating post-stroke depression. Therefore, we adopted this program to comprehensively evaluate the effect of massage on depression patients after stroke.

Condition being studied: Stroke is an acute cerebrovascular disease. Depression is a common complication of stroke. Depression after a stroke, if left untreated, may not only lead to a recurrence of the stroke, but also may cause anxiety, insomnia, cognitive decline and other mental disorders.At present, the treatment method for post-stroke depression is mainly drug therapy. A meta-analysis involving 52 studies showed that SSRI drugs can significantly reduce the disability rate and neurological deficits of patients when treating depression after stroke and improving the mood of patients. It can be seen that drug treatment has an important position. But we should also see the side effects and risks of drug treatment, and economic consumption. Studies have shown that the use of SSRI drugs increases the risk of bleeding complications and makes the elderly more likely to fall. There are also epidemiological studies that show that SSRI is also indispensable to patients' subsequent strokes. we should find a safer, cheaper, and effective treatment intervention for patients with post-stroke depression. According to research, massage can effectively improve mood, create a feeling of pleasure, and reduce the occurrence of major adverse events in stroke patients.

METHODS

Search strategy: We will retrieve all RCTs and cohort studies of massage therapy for poststroke depression from the following database, including the Web of Science,the Cochrane Library search, EMBASE, PubMed, CNKI, Chinese biomedical literature database, Chongqing VIP, and Wanfang., by November 15, 2020. Table 1 describes in detail the retrieval strategies adopted by PubMed. We will retrieve some uncompleted or unpublished trial data from the China Clinicaltrials registry and clinicaltrials.gov.

Participant or population: All the patients included in this study were poststroke patients who met the clinical diagnostic criteria for poststroke depression without age or race restrictions.

Intervention: The treatment group was mainly massage therapy.The comparison group consisted of those receiving routine care or any intervention other than massage therapy.

Comparator: All included patients met the diagnostic criteria for post-stroke depression set out in the Chinese Guidelines for the Prevention and Treatment of Cerebrovascular Diseases, "regardless of age or race".

Study designs to be included: A randomized controlled trial (RCTS) study and cohort studies of massage therapy for depression after stroke published in any language.

Eligibility criteria: In addition to individual case reports, review, summaries of experience, animal studies, and non-randomized controlled trials, this study will include all RCTS and cohort studies of massage therapy in patients with post-stroke depression, regardless of language or publication status.

Information sources: 8 electronic databases including PubMed, Web of Science, the Cochrane Database, EMBASE, China Knowledge Network (CNKI), Wanfang Data Knowledge Service Platform, VIP Chinese Science and Technology Periodical Database (VIP) and

China Biomedical Literature (CBM) Database.

Main outcome(s): Self-rating Anxiety Scale(SAS), Self-rating Depression Scale (SDS) Hamilton Depression Rating Scale (HAM-D).

Additional outcome(s): Adverse events.

Data management: The two authors will extract the following data: journal, author information, title, publication time, participant characteristics, sample size, interventions, study methods, primary and secondary outcome measures, and any adverse events, respectively. A third author will step in to address any potential differences.

Quality assessment / Risk of bias analysis: The two reviewers conducted a rigorous methodological quality assessment of the methodological characteristics of the included studies by referring to the Cochrane Collaborative Bias Risk Assessment tool.

Strategy of data synthesis: The RevMan 5.3 software will be used for data analysis. When the measured results were dichotomous, a 95% confidence interval risk ratio (RR) was used. With continuous variables as the measurement results, the weighted average difference (WMD) with CI of 95% was selected when the measurement tools were the same. Otherwise, a 95% CI standard Mean Difference (SMD) is used. $I2$ was calculated to evaluate heterogeneity across studies. $I2 < 25\%$ considered homogeneity; $25\% \leq I2 < 50\%$ considered low heterogeneity; $50\% \leq I2 < 75\%$ considered moderate heterogeneity; and $I2 \geq 75\%$ considered substantial heterogeneity. Data were analyzed using a fixed-effect model if they were homogeneous or of low heterogeneity, and a random-effect model were used if they showed moderate or substantial heterogeneity. All meta-analyses were conducted using Review Manager (RevMan) Version 5.3 software (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014).

Subgroup analysis: When significant heterogeneity exists among the tests involved, we will take into account factors such as massage mode, post-stroke depression severity, course of disease, stroke type, sample size and so on for subgroup analysis.

Sensibility analysis: Sensitivity analysis will be used to test the quality of the literature to exclude low-quality literature and to ensure the stability and reliability of the conclusions drawn from the meta-analysis.

Language: No restriction.

Country(ies) involved: China.

Keywords: massage, Post-stroke depression (PSD), protocol, systematic review.

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