INPLASY PROTOCOL

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Review Stage at time of this submission: Preliminary searches.

Conflicts of interest: None.

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

Zhang, Y[1]; Hu, S[2]; Yang, Y[3]; Kong, D[4]; Mu, Y[5]; Xiong, B[6]; He, X[7].

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 insomnia after stroke, providing the latest evidence-based medicine for the clinical treatment of insomnia after stroke.

Condition being studied: Stroke is an acute cerebrovascular disease. China has the highest incidence of stroke in the world, and it is the leading cause of death and disability among Chinese adults. Insomnia is a common complication of stroke. A meta-analysis showed that the rate of insomnia in patients after PSI was about 38.2%. Insomnia after a stroke, if left untreated, may not only lead to a recurrence of the stroke, but also may cause anxiety, depression, cognitive decline and other mental disorders. Currently, the drug therapy for post-stroke insomnia generally includes histamine 1 receptor blockers, benzodiazepines, non-benzodiazepine sleeping pills, melatonin receptor agonists, serotonin receptor agonists, etc. these medications do improve insomnia symptoms, but a range of side effects such as lethargy, delirium, drug dependence, and possible effects on nerve repair in stroke patients should not be overlooked. However, CBT, as the main non-drug therapy, has no obvious long-term efficacy. To sum up, the urgent problem to be solved is to find a safer and less side effect non-drug treatment intervention for insomnia patients after stroke. Studies have shown that massage can significantly improve the symptoms of insomniacs, giving them a pleasant feeling.

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 insomnia after stroke, providing the latest evidence-based medicine for the clinical treatment of insomnia after stroke.

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

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METHODS

Search strategy: Until October 23, 2020, the Chinese biomedical literature database, Chongqing VIP, CNKI, Wanfang, Web of Science, Cochrane Library, PubMed, EMBASE and other databases were searched, and the literature on massage intervention for post-stroke insomnia was retrieved.Keywords: stroke, insomnia, sleep disorders, massage, massage, ear acupoint massage, foot massage, random.English searches included "insomnia after a stroke" and "massage or massage therapy."This study does not limit the scope of language retrieval.In addition, we manually searched other literature, as well as unpublished research and conference materials.If test report data is unknown or lacking, we will contact the author via email.

Participant or population: All the patients included in this study were poststroke patients who met the clinical diagnostic criteria for poststroke insomnia 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 insomnia set out in the Chinese Guidelines for the Prevention and Treatment of Cerebro-vascular Diseases, "regardless of age or race".

Study designs to be included: A randomized controlled trial (RCTS) study of massage therapy for insomnia 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 of massage therapy in patients with post-stroke insomnia, regardless of language or publication status.

Information sources: Eight 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): 1. Pittsburgh Sleep Quality Index (PSQI).

Additional outcome(s): 1.Adverse events, 2. Athens Insomnia Scale (AIS), 3. The Insomnia Severity Index (ISI).

Data management: Two reviewers independently screened the literature, extracted the date, and cross-checked.If there were differences, they would discuss or listen to a third party to resolve them.The extracted data mainly include: basic characteristics: author, year of publication, sample size, course of treatment, outcome indicators, follow-up, etc. methodological characteristics: random allocation method, random scheme concealment, blind method, etc.

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: RevMan5.3 software was used for data analysis. Relative risk (RR) was used as the effect analysis statistic for binary variables, mean difference (MD) was used as the effect analysis system for continuous variables, and 95% confidence interval (95% CI) was used for interval estimation.Na into the heterogeneity between the results using chi-square test analysis (alpha test level = 0.1), and combining with quantitative judgment I2 heterogeneity is big is small, if I2 < 50%, show good homogeneity between the various research, using the fixed effects model, if I2 50% or higher, argues that the statistical heterogeneity between the results of the study is larger, should further analyze sources of heterogeneity, and the random effects model.If significant clinical heterogeneity exists, sensitivity analysis is used, or descriptive analysis only.

Subgroup analysis: Subgroup analysis will be handled according to the differences in massage methods, patient conditions, and control.

Sensibility analysis: Sensitivity analyses will be performed to verify the robustness of the review conclusions. The impacts of study design, methodological quality, and missing data will be evaluated. Sensitivity analyses were planned by studies considered being at low risk of bias.

Language: No restiction.

Country(ies) involved: China.

Keywords: massage, Post-stroke insomnia (PSI), protocol, systematic review

Contributions of each author:
Author 1 - YaJing Zhang - The author drafted the manuscript.
Author 2 - ShaSha Hu - The author provided statistical expertise.
Author 3 - YaQin Yang.
Author 4 - DeHong Kong.
Author 5 - YuTing Mu.
Author 6 - Bo Xiong.
Author 7 - XingWei He - Give funding and guidance.