INPLASY PROTOCOL

Effectiveness and safety of massage in the treatment of restless legs syndrome: protocol for systematic review and meta-analysis

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Review question / Objective: This study comprehensively searched the literature to further systematically evaluate the effectiveness and safety of massage in the treatment of restless legs syndrome, with a view to clinically treating patients with restless legs syndrome, alleviating its related clinical symptoms and preventing its further development, and providing the latest evidence-based medical evidence.

Condition being studied: Restless legs syndrome, the prevalence of 5% to 15% is reported internationally, among which women are more than twice that of men(female:male=13.9%:6.1%). Patients with restless legs syndrome are often accompanied by symptoms of insomnia, fatigue, blood pressure fluctuations, cognitive impairment, anxiety and depression, etc. which seriously affect the quality of life. Studies have shown that restless legs syndrome is associated with cardiovascular disease, stroke, and sexual dysfunction occurrence and so on. Therefore, in recent years, the treatment and research progress of restless legs syndrome has attracted the attention of scholars all over the world. On ventional treatment for restless legs syndrome, such as dopaminergic drugs, anticonvulsants and other western drugs, produces considerable beneficial medical outcomes. However, these cannot eradicate the diseases and are often accompanied by adverse effects. Massage is a Chinese nursing intervention that can effectively alleviate patients' leg discomfort, improve their sleep quality, relieve anxiety and depression. The treatment is safe and has no obvious adverse reactions.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 September 2020 and was last updated on 09 September 2020 (registration number INPLASY202090038).

INTRODUCTION

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its further development, and providing the latest evidence-based medical evidence.

Rationale: Restless legs syndrome, also known as Ekbom disease (EKD), which is often related to genetics and dopamine function in the brain, and can be secondary to many diseases such as parkinson's disease, sjogren's syndrome, rheumatoid arthritis, etc. Studies have shown that massage therapy can not only reduce the leg discomfort in patients with restless legs syndrome, but also improve the quality of sleep and relieve anxiety and depression.

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METHODS

Search strategy: 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. The retrieval time was from the time the database was builtto September 6,2020. The search uses the keyword search. Chinese search terms include restless legs syndrome, Ekbom disease, Ekbom syndrome, Massage, tuina, random. English search terms include "restless legs syndrome" 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 the test report data is unknown or lacking, we will contact the author by email.

Participant or population: All cases included in the trial were patients with restless legs syndrome and met the clinical diagnostic criteria of restless legs syndrome, without age and 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 cases included in the trial were patients with restless legs syndrome and met the clinical diagnostic criteria of the International Restless Leg Syndrome Study Group (IRLSSG) for restless legs syndrome," without age and race restrictions.

Study designs to be included: A randomized controlled trial (RCT) study on massage treatment of patients with restless legs syndrome, published in any language.

Eligibility criteria: Types of study:All randomized controlled trial (RCTs) study on massage treatment of patients with restless legs syndrome,Others such as experience report, non-RCTs, or animal trials will be excluded.

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): 1. Restless Leg Syndrome (RLS) Severity Self-Rating Scale.

Additional outcome(s): 1.The Pittsbuigh Sleep Quality Index scale(PSQI). 2. The State Anxiety Inventory (SAI). 3. The Center for Epidemiological Studies Depression (CES-D) scale. 4.Any adverse events.

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.T he 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: Two reviewers performed rigorous methodological quality evaluation of the included studies with reference to the Cochrane Collaboration Bias Risk Assessment Tool for the extracted methodological features.

Strategy of data synthesis: Meta analysis was performed using RevMan5.3 provided by the Cochrane collaboration network. Relative risk (RR) was used for the two categorical variables, and mean difference (MD) was used for the continuous variables. Both were expressed with 95% confidence intervals (CI). The heterogeneity test between the results of the included studies was performed using the I2 test.The 12 value reflects the proportion of the total variation in the effect size due to the existence of heterogeneity. 12 ? 50%, indicating that heterogeneity is more obvious. If there is no obvious

heterogeneity between the research results (I2 <50%), the fixed effect model is used to merge them; if there is significant heterogeneity (12?50%), the source of the heterogeneity is analyzed first, which may lead to heterogeneity Factors for subgroup analysis.If statistical heterogeneity exists in each subgroup without clinical heterogeneity, a random effects model is used for analysis. If the heterogeneity is too large and the results cannot be combined, a descriptive analysis is used and a sensitivity analysis is performed if necessary.

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.

Country(ies) involved: China.

Keywords: massage, restless legs syndrome, protocol, systematic review.

Contributions of each author:
Author 1 - Shasha Hu - drafted the manuscript.
Author 2 - Yajing Zhang - The author provided statistical expertis.
Author 3 - Yaqin Yang.
Author 4 - Dehong Kong.
Author 5 - Yunting Mu.
Author 6 - Bo Xiong.
Author 7 - Xingwei He - Give funding andguidance.