INPLASY PROTOCOL

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Conflicts of interest: None declared.

Acupuncture plus Massage for cervical headachea A protocol of a systematic review and meta-analysis

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Review question / Objective: This study aimed to conduct a meta-analysis of acupuncture plus massage in the treatment of cervicogenic headache chronic insomnia to clarify itsefficacy.

Condition being studied: The database of PubMed, EMbase, Cochrane library, Medicine, Web of Science, Chinese academic journals (Wanfang), Chinese knowledge resources database (CNKI), Weipu Chinese periodical service platform (VIP) and Chinese biomedical literature service system were searched for a randomized controlled trial of acupuncture combined with massage for cervical headache published up to November 2021. The primary outcomes included the overall efficiency, visual simulation score (VAS), neck activity score (ROM), quality of life score, and adverse reactions as secondary outcomes were assessed. Cochrane bias risk assessment tool was used for literature data screening and quality evaluation, and Using RevMan5.4 to collect data for statistical analysis.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 December 2021 and was last updated on 09 December 2021 (registration number INPLASY2021120049).

INTRODUCTION

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METHODS

Participant or population: Patients with a clinical diagnosis of cervical headache and have clear efficacy criteria, The diagnostic criteria refer to the Diagnostic Efficacy Standards of Traditional Chinese Medicine Diseases, Internal Chinese Medicine (7th Edition) or the cervical headache diagnostic criteria formulated by the International Headache Association; The patients' age, sex, and disease course are not limited.

Intervention: The treatment group was treatedwith acupuncture plus massage, and acupoints and frequency were not limited.

Comparator: The control group was other effective treatments for cervical headache different from acupuncture and massage, such as Western medicine alone or acupuncture alone.

Study designs to be included: (1) Study type: randomized controlled test; (2) Subjects: Patients with a clinical diagnosis of cervical headache and have clear efficacy criteria, The diagnostic criteria refer to the Diagnostic Efficacy Standards of Traditional Chinese Medicine Diseases, Internal science of Traditional Chinese Medicine (7th edition) or the cervical headache diagnostic criteria formulated by the International Headache Association; The patients' age, sex, and disease course are not limited.

Eligibility criteria: 1. Inclusion criteria(1) Study type: randomized controlled test; (2) Subjects: Patients with a clinical diagnosis of cervical headache and have clear efficacy criteria, The diagnostic criteria refer to the Diagnostic Efficacy Standards of Traditional Chinese Medicine Diseases, Internal Chinese Medicine (7th Edition) or the cervical headache diagnostic criteria formulated by the International Headache Association: The patients' age, sex, and disease course are not limited; (3) Intervention measures: the treatment group is acupuncture combined with massage, Acupuncture and massage techniques are unlimited. The control group was other effective treatments for cervical headache different from acupuncture and massage, Such as simple western medicine treatment or simple acupuncture treatment; (4) Outcome indicators: any of overall efficiency, VAS score, ROM score, quality of survival (QOL) evaluation, TCM svndrome score a n d other indicators.2.Exclusion criteria(1) Repeated published literature or non-randomized controlled trials, such as disease cases, animal tests, review, expert experience elaboration, systematic evaluation, etc.; (2) use non-standard grouping methods such as group by even numbers of cases, in order of admission, mention only random words do not explain the specific grouping methods, etc.; (3) the full text can not be obtained.

Information sources: The following databases will be searched: Web of Science, PubMed, Cochrane Library, Embase, Medicine and Medline databases. In addition, we will also collect 4 databases of China: China National Knowledge Infrastructure, China Biomedical Literature Database, VIP Database, and Wan fang Database. We selected eligible studies published up to November 2021. We will retrieve hand related literature such as replacing and supplementing some references such as medical textbooks and clinical laboratory manuals, etc; We will also retrieve relevant reference lists to identify articles with relevance to published journals, books, conference articles, and grey literature.

Main outcome(s): The overall efficiency, Visual simulation score (VAS), Neck activity score (ROM), Quality of life score was the primary outcome of cervical headache. In addition, we will carefully observe the adverse reactions of patients during acupuncture and tuinas.

Quality assessment / Risk of bias analysis:

The Cochrane Handbook version 5.1.0 was used to assess the risk of bias of the included literatures, which included the following: whether the randomization method used was standardized (generation of random sequence), allocation concealment, whether blinding was applied to implementers and subjects (blinding was applied), whether there was intention to treat analysis (detection bias), and whether there was missing outcome data (attrition bias) Seven aspects were assessed: high, moderate, or low risk of bias in the literature, whether there was selective outcome reporting (reporting bias), and other sources of bias. When an outcome index was documented at> 10, a funnel map was used for publication risk of bias analysis.

Strategy of data synthesis: The basic information extraction table was formulated with Excel in advance, and two researchers independently screened the relevant documents: the basic information included: text questions, year of publication, author name, the treatment group and the control group were included in the study cases, disease course, intervention measures, risk evaluation tools of bias and outcome indicators, etc. Crosscheck the information, and finally be determined by the corresponding author in case of differences.

Subgroup analysis: If there was high heterogeneity among the included studies, we conducted a subgroup analysis to analyze the sources of heterogeneity according to the following factors: sex, race, different treatments of control group, different methods of study quality, sample size, different methods of acupuncture

ortuina, and other possible factors affecting the results.

Sensitivity analysis: According to the recommendations of the Cochrane Handbook, to conduct a sensitivity analysis, in order to test the stability and reliability of the results of this study. The main analysis points included the impact of method quality, sample size, and missing data on the study. If there was no directional change after the sensitivity analysis, the results were stable.

Country(ies) involved: China.

Keywords: acupuncture, tuina, cervical headachea, protocol, systematic review.

Contributions of each author:

Author 1 - Fangfang Ding - The author drafted the manuscript.

Author 2 - Zhen Liu - The author provided statistical expertise.

Author 3 - Rui Li - Investigation.

Author 4 - Yan Lu - The author read, provided feedback and approved the final manuscript.

Author 5 - Chenying Wang - The author provided methodology.