

INPLASY PROTOCOL

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Complementary and alternative therapies for Tension-type headache: A protocol for systematic review and network meta-analysis

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Review question / Objective: Population: Patients diagnosed as Tension-type headache based on The International Classification of Headache Disorders established by the International Headache Society. No restrictions on age, race, sex, nationality, disease severity, disease duration. Intervention: The treatment group received complementary and alternative therapies (EMG biofeedback therapy, relaxation training, cognitive behavioural therapy, physical exercise, yoga, massage, management, TENS, Dry needling therapy, acupuncture, Chinese herbal medicine), and these interventions can be used alone or in combination. Comparison: The control group received no treatment, placebo, regular western medicine or other conventional treatment. Outcome: Primary outcomes: Pain intensity (assessed by a validated tool, such as the visual analogue scale), attack frequency (number of headache attacks per evaluation interval), duration of pain (in hours). Secondary outcomes: Quality of life, adverse reactions. Study design: The research will contain randomized controlled trials (RCTs) of complementary therapies and alternative therapies for Tension-type headache.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 March 2021 and was last updated on 24 March 2021 (registration number INPLASY202130088).

INTRODUCTION

Review question / Objective: Population: Patients diagnosed as Tension-type headache based on The International Classification of Headache Disorders

established by the International Headache Society. No restrictions on age, race, sex, nationality, disease severity, disease duration. Intervention: The treatment group received complementary and alternative therapies (EMG biofeedback

therapy, relaxation training, cognitive behavioural therapy, physical exercise, yoga, massage, management, TENS, Dry needling therapy, acupuncture, Chinese herbal medicine), and these interventions can be used alone or in combination. **Comparison:** The control group received no treatment, placebo, regular western medicine or other conventional treatment. **Outcome:** Primary outcomes: Pain intensity (assessed by a validated tool, such as the visual analogue scale), attack frequency (number of headache attacks per evaluation interval), duration of pain (in hours). Secondary outcomes: Quality of life, adverse reactions. **Study design:** The research will contain randomized controlled trials (RCTs) of complementary therapies and alternative therapies for Tension-type headache.

Condition being studied: Tension-type headache is the most common type of headache, and its prevalence is on the rise. It has a negative effect on education level, income, quality of life, which is not conducive to developing the social economy. At present, the pharmacological treatments of Tension-type headache are not the best and effective. Meanwhile, complementary therapies and alternative therapies play an essential role in relieving symptoms. Since meta-analysis cannot evaluate multiple interventions simultaneously, the network meta-analysis can compare and rank various interventions. Therefore, we propose the network meta-analysis protocol to compare the efficacy and safety of various complementary therapies and alternative therapies for Tension-type headache.

METHODS

Search strategy: The database we will search is as follows: PubMed, Cochrane Central Register of Controlled Trials, Web of Science, EMBASE, Cochrane Library, Chinese Biomedical Literature Database (SinoMed), VIP database, China National Knowledge Infrastructure (CNKI), Wanfang Database. Also, We will track the references in the meta-analysis of TTH's

complementary and alternative therapies and search for qualified studies on the World Health Organization International Clinical Trial Registry Platform (WHO ICTRP). The search period is from the establishment of the database to February 2021. Meanwhile, The search strategy will take the form of a combination of medical subject headings (MeSH) and free-text terms. The search string will be built as follows: (“Tension-type headache” [MeSH Terms] OR Tension* headache[Title/Abstract] OR headache Tension*[Title/Abstract] OR Tension* headaches[Title/Abstract] OR headaches Tension*[Title/Abstract] OR Idiopathic Headache*[Title/Abstract] OR Headache* Idiopathic[Title/Abstract] OR Stress Headache*[Title/Abstract] OR Headache* Stress[Title/Abstract] OR Psychogenic Headache*[Title/Abstract] OR Headache*Psychogenic [Title/Abstract])AND (“Complementary Therapies”[MeSH Terms] OR Therap*, Complementary[Title/Abstract] OR Complementary Medicine[Title/Abstract] OR Medicine Complementary[Title/Abstract] OR Alternative, Medicine[Title/Abstract] OR Medicine, Alternative[Title/Abstract] OR Therap*,Alternative[Title/Abstract] OR Alternative ,Therap*,[Title/Abstract]) AND (“Randomized Controlled Trials as Topic”[MeSH Terms] OR “Randomized Controlled Trial”[Publication Type] OR Clinical Trials, Randomized[Title/Abstract] OR Trials, Randomized Clinical[Title/Abstract] OR Controlled Clinical Trials, Randomized[Title/Abstract]).

Participant or population: Patients diagnosed as Tension-type headache on the basis of The International Classification of Headache Disorders established by the International Headache Society. No restrictions on age, race, sex, nationality, disease severity, disease duration.

Intervention: The treatment group received complementary and alternative therapies (EMG biofeedback therapy, relaxation training, cognitive behavioural therapy, physical exercise, yoga, massage, management, TENS, Dry needling therapy,

acupuncture, Chinese herbal medicine), and these interventions can be used alone or in combination.

Comparator: The control group received no treatment, placebo, regular western medicine or other conventional treatment.

Study designs to be included: The research will contain randomized controlled trials (RCTs) of complementary therapies and alternative therapies for Tension-type headache.

Eligibility criteria: The research will contain randomized controlled trials (RCTs) of complementary therapies and alternative therapies for Tension-type headache. Case reports, expert opinions, animal experiments, non-RCT and review papers will not be included. Moreover, the study will only search for Chinese and English document.

Information sources: The database we will search is as follows: PubMed, Cochrane Central Register of Controlled Trials, Web of Science, EMBASE, Cochrane Library, Chinese Biomedical Literature Database (SinoMed), VIP database, China National Knowledge Infrastructure (CNKI), Wanfang Database. Also, We will track the references in the meta-analysis of TTH's complementary and alternative therapies and search for qualified studies on the World Health Organization International Clinical Trial Registry Platform (WHO ICTRP). If the required information is incomplete, we will try to contact the corresponding author. If there is no reply, we will record this and extract the data available for analysis.

Main outcome(s): Pain intensity (assessed by a validated tool, such as the visual analogue scale), attack frequency (number of headache attacks per evaluation interval), duration of pain (in hours).

Additional outcome(s): Quality of life, adverse reactions.

Data management: Two researchers will independently retrieve documents according to a predetermined search strategy. We will exclude the unrelated literature by reading the abstract and title. Based on the previous step, we will further search for qualified documents by reading the full text. Then, The documents will leading-in Endnote X9 software for management. Disagreements will be solved by seeking a third independent researcher or discussing within a group. Two researchers will extract data from qualified literature and record them using Microsoft Excel 2019 software.

Quality assessment / Risk of bias analysis: Two researchers will use Cochrane Collaboration's bias risk assessment tool for quality assessment. Each aspect will be classified as "low", "high", or "unclear". In case of disagreement, they will be resolved through discussion or by seeking a third-party researcher.

Strategy of data synthesis: 1. Pairwise meta-analysis: Stata16.0 was used for paired meta-analysis to compare the literature results. Continuous data will be described by standardized mean difference (SMD) or mean difference (MD), and dichotomous data will be described by the odds ratio (OR). Besides, a 95% confidence interval (CI) will be calculated for both, and heterogeneity will be assessed based on the I² value. 2. network meta-analysis: Stata16.0 draws the network diagram, and Bayesian network meta-analysis is realized by Bayes Markov Chain Monte Carlo (MCMC) in WinBUGS1.4.3. When running the WinBUGS1.4.3, we will use the Brooks Gelman Rubin method and trace graph to evaluate the convergence of iteration. If the potential scale reduction factor (PSRF) tends to 1, it means that the convergence is better, and the conclusion is more credible. Moreover, we will use the surface under the Cumulative Ranking Curve (SUCRA) value to rank interventions. The closer the value is to 1, the therapeutic effect is better. Supposing there is a closed loop in network meta-analysis, we need to use the node splitting method to evaluate the consistency.

Subgroup analysis: If there is significant statistical heterogeneity, we will perform subgroup analysis according to various sources of heterogeneity. For example, the patients were grouped according to their age, gender and so on.

Sensitivity analysis: We will conduct sensitivity analysis by excluding literatures to determine whether the literatures affects heterogeneity. If the heterogeneity changes after excluding a document, indicating that the document affects the heterogeneity, and we will analyze the reasons. On the contrary, if there is no significant change in heterogeneity, the results is reliable.

Language: The language will be restricted to Chinese or English.

Country(ies) involved: China.

Keywords: Tension-type headache; complementary and alternative therapies; network meta-analysis.

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