

INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Effects of acupuncture treatment on post-traumatic headache after traumatic brain injury in patients: A protocol for systematic review

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Review question / Objective: The purpose of this systematic review protocol is to provide the evidence for proving the effectiveness of acupuncture for the treatment of post-traumatic headache in patients with traumatic brain injury.

Condition being studied: Post-traumatic headache (PTH) after traumatic brain injury(TBI) is a common clinical symptom, which refers to the headache that occurs after traumatic brain injury. From 2000 to 2019, the new cases of TBI in my country increased from 2.032 million to 3.310 million, an increase of 62.9%, while the number of patients increased from 2.984 million to 6.546 million, an increase of 119.4%. It can be seen that the incidence and prevalence of TBI in my country are generally increasing rapidly.

Information sources: The following electronic databases such as PubMed, Web of Science, Embase, PsycINFO, as well as the Chinese databases like Chinese Biomedicine Literature (CBM), Chinese Medical Current Content (CMCC), Chinese Scientific Journal Database (VIP), WanFang Database, and China National Knowledge Infrastructure (CNKI) will be searched from their inception to February 2022:. No language restrictions were applied in the search strategy.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 February 2022 and was last updated on 20 July 2023 (registration number INPLASY202220073).

INTRODUCTION

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METHODS

Participant or population: Adults over the age of 18 with headache after traumatic brain injury and meeting the criteria for a diagnosis of PTH will be included, Regardless of gender, race, nationality and medical institution.

Intervention: All patients who have used acupuncture or related technical interventions, such as acupuncture, electro-acupuncture, moxibustion, acupressure, acupoint injection, cupping, laser acupuncture, ear acupuncture, scalp acupuncture, acupoint bloodletting therapy, fire acupuncture, intradermal acupuncture, acupoint catgut embedding will be included in this research. All times, frequencies and durations of treatment will be eligible for inclusion.

Comparator: Trials will be included if they included any of the following control groups: conventional medication, placebo medication, sham intervention, no intervention.

Study designs to be included: Randomized control Trial, cohorts and case-control studies. Any randomized controlled trials, cohort and case-control studies that met the inclusion and exclusion criteria will be included in this study.

Eligibility criteria: (1) The patients who are determined to have a history of traumatic brain injury. (2) PTH is defined as the onset of headache within one week of head trauma or injury or within one week after an unconscious patient regains sensation and is able to report pain. (3) Meet the diagnostic criteria of traditional Chinese medicine and western medicine for

headache. (4) Those who have used other therapies with poor results. (5) Subjects who voluntarily agreed to join the project and signed the informed consent form. (6) Aged over 18 years old.

Information sources: The following electronic databases such as PubMed, Web of Science, Embase, PsycINFO, as well as the Chinese databases like Chinese Biomedicine Literature (CBM), Chinese Medical Current Content (CMCC), Chinese Scientific Journal Database (VIP), WanFang Database, and China National Knowledge Infrastructure (CNKI) will be searched from their inception to February 2022. No language restrictions were applied in the search strategy.

Main outcome(s): In its most typical form, PTH is clinically similar to other primary headache phenotypes, primarily migraine-like and tension-type headache, followed by cluster-like, cervicogenic, and other unclassified headache subtypes. The main measurement of the efficacy of acupuncture will be evaluated by Verbal Rating Scale, VRS.

Additional outcome(s): Faces pain scale-Revised (FPS-R), Visual Analog Scale (VAS), Numerical Rating Scale (NRS).

Quality assessment / Risk of bias analysis: The quality of RCT studies will be assessed by Cochrane checklist, and the quality of cohort and case-control studies will be assessed by Newcastle Ottawa Scale (NOS). Two reviewers (Yang Yang, Shaowen Hu) will extract the data and assess the quality of each study independently. Disagreements will be resolved through discussion with the third researcher.

Strategy of data synthesis: Meta-analysis will be performed using RevMan 5.3 software. $P < 0.05$ will be considered statistically significant. Fixed-effect models ($I^2 < 50\%$) or random-effect models ($I^2 \geq 50\%$) will be selected depending on the level of heterogeneity of the included studies. At the same time, sensitivity analysis and subgroup analysis will be conducted to find out the possible causes

of heterogeneity. However, after sensitivity analysis and subgroup analysis, if the data still had significant heterogeneity ($I^2 > 75\%$), the meta-analysis will not be accepted.

Subgroup analysis: When heterogeneity is exit, subgroup analyses will also be conducted to determine associations between relevant study characteristics, such as gender, study quality, sample size, age, acupuncture type and duration, headache severity at baseline, severity of impairment in history of TBI disease, time after injury, psychiatric disorders, risk of bias, etc.

Sensitivity analysis: We will conduct a sensitivity analysis if there are studies of low quality after conducting the quality assessment of the included researchers. Also, the sensitivity analysis will be performed when there is significant heterogeneity between the researches.

Language: No restriction.

Country(ies) involved: China.

Keywords: Acupuncture, post-traumatic headache, traumatic brain injury, systematic review.

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