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None declared.

Acupuncture for tension-type headache: A systematic review and meta-analysis of randomized controlled trials

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Fan, J⁷; Li, J⁸; Jin, RJ⁹.

Review question / Objective: What is the effectiveness of
acupuncture treatment for tension-type headache (TTH)?

(P) Patients - Adults diagnosed as TTH (diagnostic criteria
release by the international Headache Society).

(I) Intervention - Various acupuncture types were included
(Manual acupuncture, Electro-acupuncture, Body needling,
Scalp acupuncture, Laser acupuncture, Transcutaneous
electrical nerve stimulation).

(C) Control - Placebo, sham stimulation/acupuncture, no
treatment/usual care, western medicine, exercise. Different
type of TCM (Chinese herbs, Chinese patent drug, Tuina) will
be excluded.

(O) Outcomes - Primary outcome: headache frequency,
headache intensity. Secondary outcome: headache duration,
consumption of medication, proportion of responders (at least
50% reduction in headache frequency/intensity/score), life
quality, depression, anxiety, adverse events.

(S) Studies design - Randomized Controlled Trial.

INPLASY registration number: This protocol was registered with
the International Platform of Registered Systematic Review and
Meta-Analysis Protocols (INPLASY) on 12 March 2022 and was
last updated on 12 March 2022 (registration number
INPLASY202230047).

INTRODUCTION

Review question / Objective: What is the
effectiveness of acupuncture treatment for
tension-type headache (TTH)? **(P) Patients**
- Adults diagnosed as TTH (diagnostic
criteria release by the international

Headache Society) **(I) Intervention** - Various
acupuncture types were included (Manual
acupuncture, Electro-acupuncture, Body
needling, Scalp acupuncture, Laser
acupuncture, Transcutaneous electrical
nerve stimulation) **(C) Control** - Placebo,
sham stimulation/acupuncture, no

treatment/usual care, western medicine, exercise. Different type of TCM (Chinese herbs, Chinese patent drug, Tuina) will be excluded. (O) Outcomes - Primary outcome: headache frequency, headache intensity. Secondary outcome: headache duration, consumption of medication, proportion of responders (at least 50% reduction in headache frequency/intensity/score), life quality, depression, anxiety, adverse events. (S) Studies design - Randomized Controlled Trial.

Rationale: Acupuncture has been commonly used for the management of TTH. But evidence of acupuncture for TTH was contradictory based on the previous systematic reviews, it is essential to update insufficient clinical evidence supporting acupuncture in TTH therapy.

Condition being studied: The global prevalence of Tension-Type Headache (TTH) is 38%. TTH is the most common primary headache. According to the frequency of headache attacks, it can be divided into three subtypes, which are rare episodic tension-type headache (monthly headache <1 day), frequent (monthly headache 1 to 14 days) and chronic (monthly ≥ 15 days). The pathophysiological mechanism of tension-type headache is still not fully understood.

METHODS

Search strategy: We will search the following electronic databases: PubMed, Web of Science, Embase, Cochrane Library, Epistemonikos database, China National Knowledge Infrastructure (CNKI), The Wanfang Database, Chinese Science and Technology Periodical Database (VIP) and CBM (China Biology Medicine) from inception onwards. We combined Medical Subject Headings (MeSH) and free text words related to acupuncture and tension-type headache, to search literature in the aforementioned electronic databases. We manually searched reference lists of included articles and relevant SRs for additional eligible studies. Grey literatures were also be reviewed, such as conference proceedings and academic degree

dissertations. We searched relevant websites for all useful data (e.g. Chinese Clinical Trial Registry (ChiCTR), Clinical Trials.gov), and consulted experts in this field for possible relevant studies. There will be no restrictions on language or date of publication. We will use a Boolean search strategy with the operators AND, OR, NOT, and the search strategy will include terms describing or relating to intervention, participants, and study design.

Participant or population: Inclusion: (a) Adults (>18 years of age);(b) Patients diagnosed with TTH (diagnostic criteria release by the international Headache Society);(c) There are no restrictions on gender, age, and nationality. (d) Patients received information about the study and written informed consent. Exclusion: (a) Patients with other primary and secondary headache diseases; (b) Patients with serious somatic or psychiatric disease 1. Dr Wen-Lin Kang, School of Health Preservation and Rehabilitation, Chengdu University of Traditional Chinese Medicine, Cheng Du 621700, China 2. Dr Jian Se, School of Health Preservation and Rehabilitation, Chengdu University of Traditional Chinese Medicine, Cheng Du 621700, China 3. Dr Rong-Jiang Jin, School of Health Preservation and Rehabilitation, Chengdu University of Traditional Chinese Medicine, Cheng Du 621700, China 4. Dr Dong-Ling Zhong, School of Health Preservation and Rehabilitation, Chengdu University of Traditional Chinese Medicine, Cheng Du 621700, China 5. Dr Yu-Xi Li, School of Health Preservation and Rehabilitation, Chengdu University of Traditional Chinese Medicine, Cheng Du 621700, China 6. Dr Xiao-Bo Liu, School of Health Preservation and Rehabilitation, Chengdu University of Traditional Chinese Medicine, Cheng Du 621700, China 7. Dr Cheng-Zhi Jiang, School of Health Preservation and Rehabilitation, Chengdu University of Traditional Chinese Medicine, Cheng Du 621700, China.

Intervention: Acupuncture: We used the WHO's definition of acupuncture, as

follows: Acupuncture literally means to puncture with a needle. However, acupuncture may also involve the application of other kinds of stimulation to certain points. We included any type of commonly used acupuncture that stimulates certain points with needles, lasers, electricity, or pressure. The specific types of acupuncture therapies included in this manuscript were manual acupuncture, electro-acupuncture, body needling, ear (auricular) acupuncture, scalp acupuncture, laser acupuncture, transcutaneous electrical nerve stimulation (TENS), and acupressure. Forms 1). combined with other TCM therapy, such as warm needling, acupoint injection, needle-knife, hydro-acupuncture, moxibustion, acupoint catgut embedding, floating needle, fire needle were excluded; 2). combined with exercise or medication were excluded.

Comparator: Included: 1) Placebo or sham stimulation/acupuncture; 2) No treatment/usual care 3) Western medicine 4) Exercise. Excluded: 1) Studies that only compared different forms or methods of acupuncture and compared acupuncture with different type of TCM (Chinese herbs, Chinese patent drug, Tuina) will be excluded.

Study designs to be included: We will include randomized controlled trials, cluster RCTs, crossover RCTs. We exclude prospective cohort studies, retrospective cohort studies, non-primary studies and case reports.

Eligibility criteria: (P) Patients Adults diagnosed as TTH (diagnostic criteria release by the international Headache Society)(I) Intervention Various acupuncture types were included (Manual acupuncture, Electro-acupuncture, Body needling, Scalp acupuncture, Laser acupuncture, Transcutaneous electrical nerve stimulation) (C) Control Placebo, sham stimulation/acupuncture, no treatment/usual care, western medicine, exercise. Different type of TCM (Chinese herbs, Chinese patent drug, Tuina) will be excluded.(O) Outcomes Primary outcome: headache frequency, headache

intensity Secondary outcome: headache duration, consumption of medication, proportion of responders (at least 50% reduction in headache frequency/intensity/score), life quality, depression, anxiety, adverse events.(S) Studies design Randomized Controlled Trial.

Information sources: We will search the following electronic databases: PubMed, Web of Science, Embase, Cochrane Library, Epistemonikos database, China National Knowledge Infrastructure (CNKI), The Wanfang Database, Chinese Science and Technology Periodical Database (VIP) and CBM (China Biology Medicine) from inception onwards. We combined Medical Subject Headings (MeSH) and free text words related to acupuncture and tension-type headache, to search literature in the aforementioned electronic databases. We manually searched reference lists of included articles and relevant SRs for additional eligible studies. Grey literatures were also be reviewed, such as conference proceedings and academic degree dissertations. We searched relevant websites for all useful data (e.g. Chinese Clinical Trial Registry (ChiCTR), Clinical Trials.gov), and consulted experts in this field for possible relevant studies. There will be no restrictions on language or date of publication. We will use a Boolean search strategy with the operators AND, OR, NOT, and the search strategy will include terms describing or relating to intervention, participants, and study design.

Main outcome(s): Headache frequency and headache intensity after the treatment.

Additional outcome(s): Headache duration; Consumption of medication; Proportion of responders (at least 50% reduction in headache frequency/intensity); Life quality; Depression; Anxiety; Adverse events.

Data management: We will extract data using a predefined tabulation, and data will consist of the following: (1) relevant data regarding participant characteristics (e.g., the sample size, age, course of disease, and sex); (2) treatment time (e.g., duration,

follow-up); (3) acupuncture type (e.g., manual acupuncture, electro-acupuncture, laser acupuncture etc); (4) control group (e.g., sham, no treatment, western medicine) (5) the outcomes of the study; We will also extract data related to adverse events and adherence rates. Data presented as mean and standard error, mean and 95% confidence intervals, or median and interquartile range will be converted to mean and standard deviation. The Web Plot Digitizer will be used to extract the data presented in graph figures. In case of missing data, we will contact the authors to obtain the data. The data will be independently screened and extracted by two reviewers. Any disagreements will be resolved through discussion and adjudication by a third reviewer.

Quality assessment / Risk of bias analysis:

The study quality will be assessed independently by two reviewers. Any disagreements will be resolved through discussion and adjudication by a third reviewer. For randomized controlled trials, we will use the Cochrane risk-of-bias 2 tool (RoB 2.0). The RoB 2.0 considers bias from five domains: randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported results. Each domain is rated as either “low risk of bias”, “some concerns”, or “high risk of bias”. An overall risk-of-bias judgment for each study is derived. The risk of bias judgment for each domain is interpreted as low risk, moderate risk, serious risk, critical risk, or no information. We will use the Grades Profile as the Grading of Recommendation, Assessment, Development, and Evaluation (GRADE) system to evaluate the certainty of evidence. Five items involving risk of bias, inconsistency, imprecision, indirectness and publication bias were investigated for the clinical important outcomes.

Strategy of data synthesis: We will perform statistical analyses using Stata SE 16.0 (StataCorp LP, College Station, TX, USA). Standardized means difference (SMD) will be used for continuous data, risk ratio

(RR) will be used for the analysis of dichotomous data. All effect quantities will be expressed as 95% CIs. We will use the I-squared and Chi2 tests to evaluate the statistical heterogeneity of the included studies. We will use a random-effects model to aggregate research studies that showed serious heterogeneity, determined the inconsistency index ($I^2 \geq 50\%$), and use a fixed-effects model to merge studies in case of significant heterogeneity ($I^2 < 50\%$). We will carry out a sensitivity analysis to identify the influence of confounding parameters by the exclusion method. That is, all studies are excluded 1 by 1, and the remaining studies will be re-analyzed to determine the stability of the results. If there is no qualitative change in the combined effect showed in the results, the results are stable. Funnel plot and Egger's test will be used to analyze whether publication bias existed in the literature. The measured effects will be considered significant at $p < 0.05$.

Subgroup analysis: We conducted subgroup analysis for primary outcomes as follows: (1) treatment time, follow-up time (0-4 week, 4-8 week, 9-12 week); (2) acupuncture type (e.g., manual acupuncture, electro-acupuncture); (3) control group (e.g., sham, no treatment, western medicine); (4) subtypes of tension-type headache (episodic, frequent).

Sensitivity analysis: We will carry out a sensitivity analysis to identify the influence of confounding parameters by the exclusion method. That is, all studies are excluded 1 by 1, and the remaining studies will be re-analyzed to determine the stability of the results. If there is no qualitative change in the combined effect showed in the results, the results are stable.

Language: No language restrictions.

Country(ies) involved: China.

Keywords: Acupuncture; Tension-type headache; Systematic review; Meta-analysis; Randomized controlled trials.

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