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The efficacy of Traditional Chinese medicine-related therapies(includind acupuncture) for epilepsy: a systematic review and network meta- analysis of randomized controlled trials

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ADMINISTRATIVE INFORMATION**Support** - None.**Review Stage at time of this submission** - Preliminary searches.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY2024120017

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 4 December 2024 and was last updated on 4 December 2024.

INTRODUCTION

Review question / Objective 1. Condition or domain being studied. Traditional Chinese Medicine (TCM)-related therapies are an important component of complementary and alternative medicine, including herbal medicine, acupuncture, moxibustion, electroacupuncture, acupoint catgut embedding, and acupoint injection. These therapies are widely used in East Asia for the treatment of epilepsy and have demonstrated efficacy in some randomized controlled trials. However, research comparing the effectiveness of different TCM-related therapies for epilepsy remains limited. Therefore, we plan to conduct this comparison through a network meta-analysis.

2. Participants/population.

The patients diagnosed with epilepsy, through clear and widely recognized criteria, will be recruited regardless of gender, age, nationality, or race.

3. Intervention(s)

For the experimental groups, Traditional Chinese Medicine-related therapies (i.e. herbal medicine, acupoint-based therapies, including manual acupuncture, electroacupuncture, warm acupuncture, acupoint embedding, acupoint injection, acupoint moxibustion, acupressure) or their combinations with conventional therapies should be applied in the experimental groups, and regardless of differences in acupuncture techniques, acupoints prescription, and the duration or frequency of treatments.

4. Comparator(s)/control.

The control group may consist of Traditional Chinese Medicine combined with Western medicine therapies, purely Western medicine therapies, or blank control methods.

5. Main outcome(s).

Overall effective rate, The frequency of seizures, and adverse events.

6. Additional outcome(s).

improvement in EEG readings, time per seizure, and Quality of Life in Epilepsy-31 (QOLIE-31).

7. Types of study to be included.

Our study will include only randomized controlled trials (RCTs) evaluating Traditional Chinese Medicine (TCM)-related therapies for epilepsy, with no restrictions on population characteristics or language. Non-RCT studies, including clinical experiences, systematic reviews, conference abstracts, and case reports will be excluded.

Condition being studied Traditional Chinese Medicine (TCM)-related therapies are an important component of complementary and alternative medicine, including herbal medicine, acupuncture, moxibustion, electroacupuncture, acupoint catgut embedding, and acupoint injection. These therapies are widely used in East Asia for the treatment of epilepsy and have demonstrated efficacy in some randomized controlled trials. However, research comparing the effectiveness of different TCM-related therapies for epilepsy remains limited. Therefore, we plan to conduct this comparison through a network meta-analysis.

METHODS

Search strategy The preliminary search strategy for the databases is as follows:**

For English databases (e.g., PubMed):

#1: Traditional Chinese medicine OR TCM OR herbal medicine [MeSH]
#2: Acupuncture OR acupuncture points OR electroacupuncture OR moxibustion [MeSH]
#3: Seizure OR epilepsy [MeSH]
#4: Randomized controlled trial [MeSH]
#5: (#1 OR #2) AND #3 AND #4
For Chinese databases (e.g., CNKI):

#1: 中醫 OR 中藥 OR 中醫藥 OR 草藥 [MeSH]
#2: 針灸 OR 針刺 OR 穴位 OR 穴位按摩 OR 電針 OR 灸 [MeSH]
#3: 癲癇 [MeSH]
#4: 隨機臨床試驗 [MeSH]
#5: (#1 OR #2) AND #3 AND #4

The search strategy will be adapted to specific database syntax as needed.

Participant or population The patients diagnosed with epilepsy, through clear and widely recognized criteria, will be recruited regardless of gender, age, nationality, or race.

Intervention For the experimental groups, Traditional Chinese Medicine-related therapies (i.e. herbal medicine, acupoint-based therapies, including manual acupuncture,

electroacupuncture, warm acupuncture, acupoint embedding, acupoint injection, acupoint moxibustion, acupressure) or their combinations with conventional therapies should be applied in the experimental groups, and regardless of differences in acupuncture techniques, acupoints prescription, and the duration or frequency of treatments.

Comparator The control group may consist of Traditional Chinese Medicine combined with Western medicine therapies, purely Western medicine therapies, or blank control methods.

Study designs to be included Our study will include only randomized controlled trials (RCTs) evaluating Traditional Chinese Medicine (TCM)-related therapies for epilepsy, with no restrictions on population characteristics or language. Non-RCT studies, including clinical experiences, systematic reviews, conference abstracts, case reports, and animal studies, will be excluded.

Eligibility criteria Participants:

The study will include patients diagnosed with epilepsy based on clear and widely recognized diagnostic criteria. There will be no restrictions on gender, age, nationality, or race.

Interventions:

The experimental groups must involve Traditional Chinese Medicine (TCM)-related therapies, including herbal medicine and acupoint-based therapies (e.g., manual acupuncture, electroacupuncture, warm acupuncture, acupoint embedding, acupoint injection, acupoint moxibustion, and acupressure), or their combinations with conventional therapies. Variations in acupuncture techniques, acupoint prescriptions, and treatment duration or frequency will not be grounds for exclusion.

Comparators:

The control group may consist of:

TCM combined with Western medicine therapies, Purely Western medicine therapies, or Blank control methods (e.g., no treatment or placebo).

Outcomes:

Primary outcomes: Overall effective rate, seizure frequency, and adverse events.

Secondary outcomes: Improvements in EEG readings, time per seizure, and Quality of Life in Epilepsy-31 (QOLIE-31).

Study Design:

Only randomized controlled trials (RCTs) evaluating TCM-related therapies for epilepsy will be included. Non-RCT studies, including clinical experiences, systematic reviews, conference abstracts, and case reports, will be excluded.

Other Restrictions:

There will be no restrictions on language or geographic location. Only randomized controlled trials (RCTs) published after 1999 will be included for analysis.

Information sources A thorough search of potentially relevant literature will be conducted in eight electronic databases from their inception to December 2024: PubMed, EMBASE, the Cochrane Library, Web of Science, Chinese Scientific Journals Database (VIP), Wan Fang Database, China Biological Medicine Database (CBM), and China National Knowledge Infrastructure (CNKI). The search strategy will be developed based on MeSH terms combined with free-text keywords for English databases, and their corresponding Chinese terms for Chinese databases.

Additionally, following the snowball strategy, references from the included literature will also be screened carefully without language restrictions.

Main outcome(s) Overall effective rate, The frequency of seizures, and adverse events.

Additional outcome(s) improvement in EEG readings, time per seizure, and Quality of Life in Epilepsy-31 (QOLIE-31).

Quality assessment / Risk of bias analysis Two experienced researchers will independently evaluate the risk of bias in all included studies using the Cochrane Collaboration tool. This evaluation will focus on several key aspects: random sequence generation, assignment concealment, blinding of outcome assessors, blinding of participants and personnel, the completeness of outcome data, selective reporting, and other potential sources of bias. Each aspect will be categorized as low risk, high risk, or unclear risk. Any disagreements between the researchers will be resolved through discussions with a third senior assessor.

Strategy of data synthesis The network meta-analysis was conducted using Stata (version 18.0, Stata MP), and R software (version 4.0.3, R Foundation for Statistical Computing). To compare various clinical outcomes of different TCM methods, we utilized the odds ratio (OR) with the corresponding 95% confidence interval (CI), the

mean difference (MD) with its respective 95% CI and the standard mean difference (SMD) with its respective 95% CI. A standard meta-analysis of directly compared treatments in randomized controlled trials was performed using a Bayesian random effects model. Convergence was assessed using Brooks-Gelman-Rubin diagnostic plots and trace plots. Additionally, an I^2 value of less than 50% indicates no significant heterogeneity, while an I^2 value greater than 50% suggests significant heterogeneity. The stability of the results was evaluated through sensitivity analysis by sequentially excluding each study. We employed the surface under the cumulative ranking (SUCRA) probability to represent the effectiveness or safety of each intervention as a percentage, indicating the best option in the absence of uncertainty. The node splitting method was applied to assess inconsistency.

Subgroup analysis To assess whether the results were influenced by study characteristics, we will utilize Stata (version 17.0, Stata MT), and R software (version 4.0.3, R Foundation for Statistical Computing) to conduct subgroup analysis and meta-regression analysis based on the following variables: acupuncture related therapies, herbal medicines, western medicines.

Sensitivity analysis To evaluate the robustness of the results, sensitivity analysis will be conducted by excluding studies with a high risk of bias, using a random-effects model instead of a fixed-effects model, and removing studies with extreme outliers. If significant heterogeneity exists, subgroup analyses will also be performed. The impact of these adjustments on the pooled estimates will be assessed to determine the stability of the findings.

Country(ies) involved The study is being carried out in Taiwan.

Keywords seizure; epilepsy; acupuncture; acupoint; Chinese herbal medicine; moxibustion; electroacupuncture; acupoint catgut embedding; meridians.

Contributions of each author

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