INPLASY PROTOCOL

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Review Stage at time of this submission: Preliminary searches.

Conflicts of interest: None declared.

Acupuncture combined with traditional Chinese medicine for allergic rhinitis: systematic review and meta-analysis

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Review question / Objective: In our study, we will perform the first systematic review and meta-analysis to explore the effectiveness and safety of acupuncture combined with TCM for AR.

Condition being studied: Allergic rhinitis (AR) is a prevalent yet underappreciated inflammatory disorder of nasal mucosa, which is characterized by pruritus, sneezing, rhinorrhoea, and nasal congestion, some studies have pointed out that if combine Traditional Chinese medicine (TCM) with acupuncture, which can enhance the effect of acupuncture and moxibustion.

Information sources: Moreover, we will filter relevant medical journals and magazines to clarify literature which is not included in the electronic databases. Meanwhile, clinical trials registries, like the WHO International Clinical Trial Registry Platform, Chinese Clinical Registry, and ClinicalTrials.gov, will be searched for ongoing trials with unpublished data. The reference lists of all potential publications, including relevant systematic reviews, will be manually retrieved and reviewed to further locate additional trials. Incomplete data will be obtained via contacting the corresponding authors.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 April 2021 and was last updated on 16 April 2021 (registration number INPLASY202140083).

INTRODUCTION

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inflammatory disorder of nasal mucosa, which is characterized by pruritus, sneezing, rhinorrhoea, and nasal congestion, some studies have pointed out that if combine Traditional Chinese medicine (TCM) with acupuncture, which can enhance the effect of acupuncture and moxibustion.

METHODS

Search strategy: PubMed, Web of science, EMBASE, the Cochrane library, Chinese National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM), WanFang Database.

Participant or population: Studies that enrolled patients with AR, regardless of gender, age, race, or nationality, who received acupuncture therapy with Traditional Chinese medicine will be included.

Intervention: We will consider studies evaluating the following treatments including body acupuncture, scalp acupuncture, warm needle acupuncture, combine with Traditional Chinese medicine.

Comparator: We will include and classify the comparators in study as follows: (1) acupuncture combine with TCM versus TCM, (2) acupuncture combine with TCM versus acupuncture, (3) acupuncture combine with TCM versus no treatment. Articles comparing different acupoints or different forms of acupuncture will be excluded.

Study designs to be included: Only randomized controlled trials (RCTs) involving acupuncture combine with Traditional Chinese medicine, placebo treatment. Language of literature will be limited to Chinese and English. Studies that mentioned the term of "randomization" will also be considered.

Eligibility criteria: Intervention will include any type of acupuncture combined with TCM for allergic rhinitis. Information sources: Moreover, we will filter relevant medical journals and magazines to clarify literature which is not included in the electronic databases. Meanwhile, clinical trials registries, like the WHO International Clinical Trial Registry Platform, Chinese Clinical Registry, and ClinicalTrials.gov, will be searched for ongoing trials with unpublished data. The reference lists of all potential publications, including relevant systematic reviews, will be manually retrieved and reviewed to further locate additional trials. Incomplete data will be obtained via contacting the corresponding authors.

Main outcome(s): Clinical efficacy, including total effective rate or cure rate, and recurrence rate will be accepted as the primary outcomes.

Additional outcome(s): The Rhinoconjunctivitis quality of life questionnaire (RQLQ) score, symptom score (nasal congestion, snot, sneezing) will be used as secondary outcomes.

Quality assessment / Risk of bias analysis: With the Cochrane Collaboration's tool for risk of bias assessment in all included

risk of bias assessment in all included studies. The following domains for risk of bias will be evaluated; sequence generation, allocation sequence concealment, blinding of participants and personnel and outcome assessors, incomplete outcome data, selective outcome reporting, and other sources of bias. The judgment on these items will be classified into three levels: "low risk of bias," "high risk of bias," or "unclear risk of bias." The conflicts or any discrepancies will be resolved by discussion or will be judged by another reviewer to achieve the consensus.

Strategy of data synthesis: Clinical data will be imported into the RevMan software (V5.4) to perform data synthesis, and the significance threshold will be P <0.05 on two sides. A forest plot for each parameter will be constructed to indicate the weight ratio of each incorporated study.

Subgroup analysis: If data is available, a subgroup analysis will be conducted according to variations in the characteristics of the trial participants and acupuncture combine with TCM treatment. When considerable heterogeneity is detected in previous analysis, a subgroup analysis will be performed if necessary.

Sensitivity analysis: Sensitivity analysis will be conducted to monitor the robustness of primary decision made in the review process. Several decision nodes, such as sample size, methodological weakness, and missing data, will be considered. The results of the sensitivity analysis will be presented in summary tables. The risk of bias in the review process as indicated by the results of the sensitivity analysis will be discussed.

Language: Without any language or publication status restrictions.

Country(ies) involved: China.

Keywords: Allergic rhinitis, Meta-analysis, TCM, acupuncture.

Contributions of each author:

Author 1 - Le Yan - The author drafted the manuscript.

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Author 3 - Lintong Dai - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.

Author 4 - Jun Feng - The author read, provided feedback and approved the final manuscript.