

# INPLASY PROTOCOL

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None declared.

## Efficacy and safety of HuaYu TongFu Method combined with acupuncture in the treatment of Acute Exacerbation of Chronic Obstructive Pulmonary Disease: A protocol for systematic review and meta-analysis

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**Review question / Objective:** This study is the protocol for a systematic review to evaluate the efficacy and safety of HuaYu TongFu Method combined with acupuncture in the treatment of Acute Exacerbation of Chronic Obstructive Pulmonary Disease. we conducted a systematic review and meta-analysis of published randomized clinical trials (RCTs) of such combined therapy in the treatment of AECOPD, It provides a reliable scientific basis for clinicians to use this approach to treat AECOPD.

**Condition being studied:** Chronic obstructive pulmonary disease is the third leading cause of death worldwide. AECOPD is the most common cause of hospitalization and death in patients with COPD. As lung function deteriorates and the disease progresses, the risk of alveolar hypoxia and consequent hypoxemia increases. Inflammation plays an important role in the progression of AECOPD. Modern medicine mainly treats AECOPD by anti-inflammatory, relief of airway spasm, glucocorticoids, inhalants and other methods. Long-term application can easily lead to bacterial flora imbalance and drug resistance in patients. Comparatively, traditional Chinese medicine and acupuncture therapy are safe and effective. To assess the therapeutic efficacy and safety of HuaYu TongFu Method combined with acupuncture in AECOPD, we created a protocol for a systematic review to inform future clinical applications.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 September 2022 and was last updated on 25 September 2022 (registration number INPLASY202290114).

### INTRODUCTION

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Pulmonary Disease. we conducted a systematic review and meta-analysis of published randomized clinical trials (RCTs) of such combined therapy in the treatment of AECOPD, It provides a reliable scientific basis for clinicians to use this approach to treat AECOPD.

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## METHODS

**Search strategy:** We conducted a systematic search for relevant documents in the Chinese and English databases, and the search time is limited to October 1, 2020. The following eight databases are included : PubMed, EMBASE, Web of Science, The Cochrane Library, Chinese Biomedical Literature Database (CBM), Chinese National Knowledge Infrastructure (CNKI), Chinese Science and Technology Periodical Database (VIP), Wanfang Database. AECOPD, acupuncture, HuaYu TongFu were selected as key words or theme words respectively. Secondary search included, COPD and Traditional Chinese medicine.

**Participant or population:** ALL patients who have been diagnosed with AECOPD, without regard to region, race, sex, age,

education, course of disease, or duration of treatment, will be included.

**Intervention:** All patients enrolled in the study received conventional treatment for AECOPD. On this basis, the intervention group was given HuaYu TongFu Method combined with acupuncture.

**Comparator:** All patients included in the study received routine treatment for AECOPD.

**Study designs to be included:** The only randomized controlled trial was included. Non-randomized controlled trials and uncontrolled clinical trials will be excluded. Whether single-blind, double-blind, or unblinded.

**Eligibility criteria:** Evidence from the International Evidence-based Medicine / Cochrane Collaboration Volume design : (1) randomized controlled trials were used in this study Trial, RCT), with or without assignment hiding and blinding; (2) The control group received conventional western medicine treatment, The treatment group took basal This treatment plus HuaYu TongFu Method combined with acupuncture. (3) conform to the public Recognized and authoritative diagnostic criteria for AECOPD. Exclusion criteria (1) Do not meet or have no diagnostic criteria; (2) No According to the group, or the test design is flawed, or the statistical method is improper; (3) Not available Literature on outcome indicators; (4) Animal experiment, review, experience summary, case report, Case review and retrospective study.

**Information sources:** We conducted a systematic search for relevant documents in the Chinese and English databases, and the search time is limited to October 01, 2022. The following eight databases are included : PubMed, EMBASE, Web of Science, The Cochrane Library, Chinese Biomedical Literature Database (CBM), Chinese National Knowledge Infrastructure (CNKI), Chinese Science and Technology Periodical Database (VIP), Wanfang Database. Relevant journals were searched to trace the references included in the

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study. Other resources will be searched if necessary.

**Main outcome(s):** The primary outcome is the Forced vital capacity(FVC), Forced expiratory volume in one second(FEV1.0), FEV1/FVC, White blood cell(WBC), Adverse reactions and adverse events.

**Data management:** Data extraction was conducted independently by 2 reviewers in accordance with the preset standardized data extraction form. If there is any disagreement or doubt, the decision should be made after discussion or third party opinion should be consulted. The extracted information includes the following contents: the basic information included in the study, such as the research title, first author, published journal, etc; baseline characteristics of the study subjects and intervention measures; the key elements of bias risk assessment; outcome indicators and outcome measurement data concerned.

**Quality assessment / Risk of bias analysis:** Two searchers searched the literature independently and checked one by one Include the study. If there is disagreement about the inclusion of the study, consult the expert to decide Decide whether to include it and try to avoid missed etection. Cochrane systems reviewers were used Volume 5.1 Bias risk Assessment tool, the included literature was qualifies from the following six aspects Quantitative evaluation:(1) whether random sequence generation is sufficient;(2) Whether the clocation is hidden; (3) Whether blind method is used;(4) Whether the result data is complete;(5) Selective reporting; (6) Whether there is publication bias.

**Strategy of data synthesis:** Two authors will independently appraise the methodological quality of each trial in six dimensions : selection bias , performance bias, detection bias, attrition bias, reporting, and other biases. Any disagreements will be resolved through discussions between the two authors or consultation with a third researcher . Articles not made available with complete clinical data will be excluded

after several attempts have been made to contact the authors of those studies.

**Subgroup analysis:** Due to potential heterogeneity that may adversely impact results of this study,The influence of different dosage forms, intervention forms and treatment methods should be considered.If a meta-analysis cannot be performed, we will conduct a descriptive analysis instead.

**Sensitivity analysis:** A sensitivity analysis will be performed to assess the robustness of the final set of results. If the results are found to be unstable, studies with a high risk of bias will be excluded.

**Country(ies) involved:** China.

**Keywords:** acute exacerbation of chronic obstructive pulmonary, acupuncture, HuaYu TongFu method, meta-analysis, protocol, systematic review.

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