INPLASY PROTOCOL

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Review Stage at time of this submission: Preliminary searches.

Conflicts of interest: None declared.

Efficacy and safety of acupuncture combined with Chinese herbal medicine in the treatment of chronic obstructive pulmonary disease: A protocol for a systematic review and meta-analysis

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Review question / Objective: The purpose of this review is to evaluate the efficacy and safety of acupuncture combined with Chinese herbal medicine in the treatment of COPD. Our goal is to publish this review in a peer-reviewed journal.

Condition being studied: Chronic obstructive pulmonary disease (COPD) is a common and frequently occurring disease of the respiratory system. The prevalence rate of COPD is increasing year by year. It is often complicated with other diseases, which has a great impact on the prognosis. Long-term use of bronchodilators and anti-inflammatory drugs will lead to drug resistance. The incidence of COPD and its complications is still on the rise. COPD has become a global public health problem endangering human health. The combination of acupuncture and Chinese herbal medicine in the treatment of chronic obstructive pulmonary disease is one of the commonly used treatments in China. However, we did not find any meta analysis of their synergism. Therefore, the purpose of this systematic review and meta-analysis is to evaluate the efficacy and safety of acupuncture combined with Chinese herbal medicine in the treatment of chronic obstructive pulmonary disease.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 March 2022 and was last updated on 25 March 2022 (registration number INPLASY202230145).

INTRODUCTION

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METHODS

Participant or population: All patients who meet the diagnostic criteria of COPD were included. The diagnostic criteria refer to the World Health Organization, the Global chronic obstructive Pulmonary Disease Initiative or the COPD guidelines of the Chinese Medical Association. The age is greater than or equal to 18 years old and is not restricted by gender, region, race, TCM syndrome and other factors. We will rule out patients with other respiratory diseases, such as asthma, interstitial lung disease, respiratory failure or other chronic lung diseases.

Intervention: The treatment group received acupuncture combined with Chinese herbal medicine.

Comparator: The control group was treated with other drugs or therapy, or routine treatment with western medicine.

Study designs to be included: All included literatures should be clinical randomized controlled trials (RCT) of acupuncture combined with Chinese herbal medicine in the treatment of COPD. The language is unlimited, not limited by the time and whether the blind method is adopted or not. We will exclude any other studies, such

as observational studies, non-randomized controlled studies, animal trials, crossover studies, personal experience summaries and case reports.

Eligibility criteria: We will determine the inclusion criteria and exclusion criteria for this study in accordance with the PICOS principles(population, intervention, comparison, outcome, study design).2.3.1. Types of studiesAll included literatures should be clinical randomized controlled trials (RCT) of acupuncture combined with Chinese herbal medicine in the treatment of COPD. The language is unlimited, not limited by the time and whether the blind method is adopted or not. We will exclude any other studies, such as observational studies, non-randomized controlled studies, animal trials, crossover studies, personal experience summaries and case reports.2.3.2. Types of participantsAll patients who meet the diagnostic criteria of COPD were included. The diagnostic criteria refer to the World Health Organization, the Global chronic obstructive Pulmonary Disease Initiative or the COPD guidelines of the Chinese Medical Association. The age is greater than or equal to 18 years old and is not restricted by gender, region, race, TCM syndrome and other factors. We will rule out patients with other respiratory diseases, such as asthma, interstitial lung disease, respiratory failure or other chronic lung diseases.2.3.3. Types of interventions and comparisonsThe treatment group received acupuncture combined with Chinese herbal medicine. The control group was treated with other drugs or therapy, or routine treatment with western medicine. There are no requirements for the time, frequency, dose and course of treatment.

Information sources: These studies come from databases such as Cochrane Library, Embase, PubMed, Web of Science, Chinese National Knowledge Infrastructure(CNKI), Chinese Biomedical Literature Database (CBM), Wanfang database, Chinese Scientific Journal Database(VIP), and so on. The time for inclusion of the literature is for each database to be established until

March 20, 2022. Before literature retrieval, we conducted professional training and study on literature retrieval skills and matters needing attention, and after two pre-checks, finally formulated the retrieval strategy. Retrieve the database through the combination of subject words and free words Take PubMed as an example, the specific retrieval strategy is shown in Table 1, and the retrieval formula is appropriately adjusted according to the characteristics of other databases. We will also search the World Health Organization's International Clinical trial Registration platform to track ongoing or completed clinical studies. If the included study lacks relevant data, we will contact the relevant researchers to obtain the required data. If the required information is not available, the data will be excluded from the analysis and explained in the discussion section. At the same time, we will manually search the list of all references from related system reviews to avoid missing high-quality randomized controlled trials that meet the criteria.

Main outcome(s): The primary outcomes include total efficacy and Lung function (postbron-chodilator forced expiratory volume in 1 second (FEV1), forced vital capacity (FVC), and FEV1/FVC.)

Additional outcome(s): Secondary outcomes include the following: (1) All-cause mortality (2) quality of life (COPD assessment test, St. chronic respiratory questionnaire, George respiratory questionnaire, etc) (3) Six-minute walking distance (4) Adverse events. If other results are reported in eligible studies, they will be extracted and reported.

Quality assessment / Risk of bias analysis: The two researchers will use the Cochrane risk bias assessment tool to assess all bias risks included in the study and cross-validate the results.If there is a difference of opinion, decide in consultation with the third researcher until a consensus is reached. The specific evaluation includes the following six aspects: random sequence generation method; whether allocation concealment is used; whether the subject and the intervention provider

are blinded; whether the result evaluator is blind; whether the result data is complete; Whether selective results reporting and other sources of bias. Each aspect will be rated as uncertain, low and high risk. We will evaluate the level of evidence quality of all results according to Grading of Recommendations, Assessment, Development and Evaluation(GRADE). The quality of the evidence will be assessed on the basis of five factors, including study limitations, effect consistency, imprecision, indirectness, and publication bias. The quality of the evidence will be classified as high, medium, low and very low.

Strategy of data synthesis: 2.5.1. Selection of studies. Two researchers (Andong Li, Shilin Liu) conducted literature retrieval according to the retrieval strategy developed in advance, and screened the literature according to the inclusion and exclusion criteria. Import the literature retrieved from the database into the Endnote X9 software, and make a preliminary screening by reading the title and abstract. Delete all meeting minutes, guides, letters and other documents, as well as duplicate documents. Then through downloading and reading the full text for further screening. The two researchers cross-check that any differences can be resolved through consultation, and if there is no consensus, consult with the third researcher (Tan Wang) and make a final agreement. The roadmap studied is based on the PRISMA flow chart, as shown in figure 1. 2.5.2. Data extraction. Two researchers extracted independent data according to the pre-designed extraction table according to the Cochrane Handbook for Systematic Reviews of Intervention. The extracted data include four aspects: basic information included in the literature, basic characteristics of patients, intervention measures, outcome indicators and so on. If there is missing or unclear information in RCT, we will try to contact the author of the literature to obtain data. Any dissenting opinions will be dealt with through consultation or consult a third researcher to resolve the differences.

Subgroup analysis: Subgroup analysis will be used to explore potential factors leading to significant heterogeneity. If a high degree of heterogeneity is found in the study, we conduct a subgroup analysis to explore the source of heterogeneity. To explore the differences in race, age, country, gender, different forms of intervention and so on.

Sensitivity analysis: Sensitivity analysis will be used to test the stability and robustness of the findings. By excluding studies with a high risk of bias or a numerical distance from the rest of the data. If the heterogeneity remains unchanged after excluding individual literatures, it shows that our research results are relatively robust. If heterogeneity changes after excluding a study, then this study may be the source of heterogeneity. We will further analyze and explain the root causes of heterogeneity.

Country(ies) involved: China.

Keywords: acupuncture, Chinese herbal medicine, Chronic Obstractive Pulmonary Disease, meta-analysis, protocol, safety.

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