INPLASY PROTOCOL

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None declared.

Effectiveness and safety of acupuncture versus conventional therapy for exercise intolerance in patients with chronic obstructive pulmonary disease: protocol for a systematic review

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Review question / Objective: **Limited motor ability is common in patients with chronic obstructive pulmonary disease (COPD), which seriously impairs the quality of life and prognosis of patients. Acupuncture has been widely used in the treatment of COPD, but its effectiveness and safety in improving motor ability has not yet been evaluated. The purpose of this study is to draw up a protocol for systematic review and meta-analysis to evaluate the efficacy and safety of acupuncture for COPD exercise intolerance.**
Information sources: **We will systematically search the following electronic databases from inception to August 31, 2021: PubMed, Medline, Web of Science, Cochrane Central Register of Controlled Trials, Springer, EMBASE, the China National Knowledge Infrastructure Database, Wan fang database, the Chinese Scientific Journal Database, and Chinese Biomedical Literature Database.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 April 2021 and was last updated on 25 April 2021 (registration number INPLASY202140131).

INTRODUCTION

Review question / Objective: **Limited motor ability is common in patients with chronic obstructive pulmonary disease (COPD), which seriously impairs the quality of life and prognosis of patients. Acupuncture has been widely used in the treatment of COPD, but its effectiveness and safety in improving motor ability has not yet been evaluated. The purpose of this study is to draw up a protocol for systematic review and meta-analysis to evaluate the efficacy and safety of acupuncture for COPD exercise intolerance.**

Condition being studied: Acupuncture, as a traditional Chinese non-pharmaceutical therapy, is widely accepted in the clinical prevention of inflammatory diseases. It is worth noting that acupuncture has been recommended and used in the treatment of COPD patients in China. COPD is a worldwide public health challenge because of its high prevalence, mortality and disability, leading to significant economic and social burden. Many systematic reviews (SRs) /meta-analyses (MAs) evaluated the effect of acupuncture on COPD and confirmed the role of acupuncture in improving patients' quality of life and dyspnea. Recently, with the in-depth study of COPD, motor ability has been regarded as a more important prognostic indicator, and a large number of high-quality clinical randomized controlled trials have emerged. It is necessary to evaluate the effectiveness and safety of acupuncture intervention for COPD motor ability, in order to provide more powerful evidence for the treatment of COPD. Therefore, in this review, we carried out a systematic evaluation of the effectiveness and safety of acupuncture intervention on COPD motor ability.

METHODS

Search strategy: We will search the clinical trials, the clinical trial registrations, potential gray literatures, relevant conference abstracts and reference list of identified studies. Two independent authors will complete the literature selection, data extraction, and quality assessment. Either the fixed-effects or random-effects model will be used for data synthesis based on the heterogeneity test. Changes in exercise ability will be evaluated as the primary outcome. Pulmonary function, arterial blood gas tensions, symptom assessment, quality of life, medication usage, exacerbations, and adverse events will be assessed as the secondary outcomes. The RevMan V.5.3.5 will be used for Meta-analysis.

Participant or population: Patients who were diagnosed with COPD at all stages of the study were classified as subjects, regardless of their sex, race, educational level, nationality or economic status. Self-report-based research for COPD diagnosis will also be considered, depending on the number of studies retrieved. Subjects with chronic cough and wheezing symptoms caused by other causes, such as tuberculosis, cancer and irritant gas allergy, will be excluded. At the same time, subjects with underlying diseases, such as osteoarthritis, which may lead to decreased motor ability, will also be excluded.

Intervention: The control group: basic treatment, including routine medication and health education, was not allowed to accept any form of acupuncture treatment during the study period. The treatment group will receive the type of acupuncture treatment according to the routine course of treatment, including manual acupuncture, body acupuncture, electroacupuncture, dermal needle, auricular acupuncture, scalp acupuncture, ocular acupuncture, fire needling, warm needling, and plum blossom needle. Any test using non-penetrating acupoint stimulation (e.g. acupoint pressure, massage, percutaneous nerve stimulation, magnet and ultrasound therapy) to test acupuncture and moxibustion will be excluded. At the same time, trigger point injection of any drug was excluded. In addition, there were no restrictions on the intervening time, frequency and follow-up.

Comparator: Routine treatment alone (consist of fluid resuscitation, source control, antibiotic therapy and organ support therapy, et al).

Study designs to be included: Systematic reviews/meta-analyses of randomized controlled trials.

Eligibility criteria: All Chinese and English randomized controlled trials (RCT) related to acupuncture intervention in COPD will be included. Quasi-randomized controlled trials, cluster randomized trials, case reports and experimental studies will be excluded.

Information sources: We will systematically search the following electronic databases from inception to August 31, 2021: PubMed, Medline, Web of Science, Cochrane Central Register of Controlled Trials, Springer, EMBASE, the China National Knowledge Infrastructure Database, Wan fang database, the Chinese Scientific Journal Database, and Chinese Biomedical Literature Database.

Main outcome(s): The primary outcomes of this review will include: 1. Cardiopulmonary exercise test, incremental walking test, unsupported upper limb exercise test. 2. Constant work rate endurance test, endurance shuttle walking test, 6-min pegboard and ring test. 3. Six-minute walk test, 30 seconds sit-to-stand test. 4. Respiratory muscle strength (maximal inspiration pressure, maximal expiratory pressure). 5. Upper and lower limb muscle strength and mass.

Additional outcome(s): The secondary outcomes will include: 1. Pulmonary function, arterial blood gas tensions (arterial oxygen pressure of carbon dioxide) 2. Symptom assessment: modified British Medical Research Council, Modified Brog Dyspnea Scale, visual analogue scale. 3. Health-related quality of life: Medical Outcomes Study 36-Item Short Form (SF-36), Chronic Respiratory Disease Questionnaire (CRQ), St. George's Respiratory Questionnaire (SGRQ), COPD assessment test, Chinese Chronic Respiratory Questionnaire. 4. Number of reported adverse events associated with the use of acupoints stimulation. 5. Number of exacerbations. 6. Medication usage.

Quality assessment / Risk of bias analysis: The risk and bias in included studies will be assessed by two review authors will independently use the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions. The following 7 domains in the Cochrane "Risk of bias tool" will be assessed: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, blinding incomplete outcome data, selective reporting, and other bias. Each potential bias test is classified as high, low and unclear. Any differences that arise in the course of the study will be resolved through discussion or by requiring the third author to make a final decision.

Strategy of data synthesis: RevMan V.5.3.5 provided by Cochrane Collaboration will be used for data analysis and synthesis. Continuous data will be expressed as MD/SMD with 95% CIs, while the dichotomous outcomes will be presented as RR with 95% CIs. When I2 <50%, the fixed effect model will be adopted to analyze. Otherwise, the random effect model will be selected. In addition, the sensitivity analysis and subgroup analysis will be used to explore the causes of heterogeneity.

Subgroup analysis: If substantial heterogeneity is proven to exist, we will conduct subgroup analysis based on the age of patients, different types of acupuncture therapies, duration of treatment, frequency of treatment and the degree of COPD severity.

Sensitivity analysis: Sensitivity analyses will be conducted to test the robustness and reliability of the results if there are sufficient studies included. The sensitivity analysis focuses on research characteristics or types such as methodological quality, and examines the effects of total effects by excluding certain low quality studies or unblinded studies.

Country(ies) involved: China.

Keywords: chronic obstructive pulmonary disease, protocol, systematic review, acupuncture, exercise intolerance.

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