INPLASY PROTOCOL

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Review Stage at time of this submission: **Formal screening of search results against eligibility criteria.**

Conflicts of interest:
None declared.

Effectiveness and safety of Qingjin Huatan Capsule for acute exacerbation of Chronic Bronchitis or Chronic Obstructive Pulmonary Disease in adults: a systematic review and meta-analysis

Hong, Z[1]; Liu, Y[2]; Fang, HY[3]; Yu, B[4]; Zhang, HC[5].

Review question / Objective: **To determine the effectiveness and safety of Traditional Chinese Medicine-Qingjin Huatan Decoction in the treatment of acute exacerbations ofChronic Bronchitis(CB) or Chronic Obstructive Pulmonary Disease (COPD)in adults.**

Condition being studied: **Chronic obstructive pulmonary disease (COPD) is currently the fourth leading cause of death in the world. There is worldwide concern about the high incidence of COPD and the severe economic and social burden it poses. Recurrent exacerbations of chronic bronchitis or COPD are a major factor in the progression of the disease. There are many treatments and medications available for this disease, including glucocorticoids, bronchodilators, and antibiotics. However, these methods still do not meet the needs of patients with CB or COPD. Patients can benefit from other treatments, such as herbal medicine. In recent years, Qingjin Huatan decoction has been widely used for respiratory diseases (e.g. bronchial asthma, chronic obstructive pulmonary disease, etc.). The results show that it can reduce clinical symptoms of CB or COPD exacerbations and shorten the course of the disease improving the lung function of patients. However, there is little evidence about its effectiveness and safety in patients with CB or COPD. Therefore, the purpose of this study was to conduct a systematic review to investigate the efficacy and safety of Qingjin Huatan decoction in adults with CB or COPD exacerbations.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 September 2022 and was last updated on 17 September 2022 (registration number INPLASY202290075).

INTRODUCTION

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METHODS

Participant or population: Participants who meet the diagnostic criteria of CB or COPD will be included, including subjects with CB as defined by the British MedicalResearch Council, COPD as defined by the criteria of the AmericanThoracic Society, the Global Initiative for Chronic Obstructive Lung Disease(GOLD), the European Respiratory Society, or the WorldHealth Organization (WHO). Participants who meet the diagnostic criteria of CB or COPD will be included including subjects with CB as defined by the British MedicalResearch Council,COPD as defined by the criteria of the AmericanThoracic Society the Global Initiative for Chronic Obstructive Lung Disease(GOLD),the European Respiratory Society or the WorldHealth Organization (WHO).

Intervention: On the basis of conventional therapy, Qingjin Huatan Decoction was added.

Comparator: Comparative interventions are defined as treatment of CB or COPD exacerbations based on COPD treatment published by the Global Initiative for Chronic Obstructive Lung Disease (GOLD) or the Chinese Medical Association, including glucocorticoids, bronchodilators, antibiotics, etc. Qingjin Huatan decoction was added to the traditional therapy. Comparative interventions are defined as treatment of CB or COPD exacerbation based on the Global Initiative for Chronic Obstructive Lung Disease (GOLD) or COPD treatment published by the Chinese Medical Association, including glucocorticoids, bronchodilators, antibiotics, etc.

Study designs to be included: RCTs.

Eligibility criteria: Exclusion criteria also included case report case series and observational studies. exclusion criteria for RCTs also included case report case series and observational studies.Exclusion criteria also include case reports case series and observational studies. RCTsExclusion criteria also include case reports case series and observational studies.RCTs.

Information sources: We will search the following electronic databases for studies on CB or COPD treatment uploaded since their inception until September 9, 2022. ...Cochrane Central Register of Controlled Trials (CENTRAL). -PubMed (1966 to September 2022) -Web of Science (1986 to September 2022) -EMBASE (1980 to September 2022) -China Biomedical Database (1975 to September 2022) (http://www.sinomed.ac.cn). China National Knowledge Infrastructure (CNKI) (1979 to September 2022) (http://www.cnki.net/) VIP Database (1979-September 2022) (http://www.cqvip.com/). Wanfang Database (1980- September 2022) (http://wwwwanfangdata.com.cn). We will search the following electronic databases for studies on CB or COPD treatment uploaded

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since their creation until September 9, 2022.

Main outcome(s): Inflammatory factors; pulmonary function; Adverse reaction.

Quality assessment / Risk of bias analysis: Two reviewers(Hong Z, Liu Y) independently assessed the risk of bias for each included trial according to the Cochrane Handbook for Systematic Reviewers of Interventions version 5The items included random sequence generation(selection bias), allocation concealment(selection bias), blinding of participants and personnel(performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias),selective reporting(reporting bias),and baseline data comparability (other bias). Each item was categorized as low/unclear/high risk of bias. Disagreements were resolved by discussion, with involvement of a third review author (Zhang HC) when necessary. In addition, we used the grading of recommendations assessment, development and evaluation(GRADE) approach to evaluate the quality of included evidences.

Strategy of data synthesis: Continuous results will be expressed as mean difference (MD) and dichotomous results as risk ratio (RR), both with 95% confidence intervals (CI). We will use a random-effects model to estimate the overall effect rather than a fixed-effects model because a random-effects model provides more conservative results by assessing study outcomes based on within-trial and between-trial differences.

Subgroup analysis: Subgroup analysis will be performed according to the different diagnoses of the patients.

Sensitivity analysis: The sensitivity analysis was also performed by removing each study one at a time to evaluate the stability of the results.

Country(ies) involved: China.

Keywords: Qingjin Huatan Decoction; COPD; CB; RCTs; systemic review; meta analysis.

Contributions of each author:
Author 1 - Zheng Hong.
Author 2 - Ying Liu.
Author 3 - HanYu Fang.
Author 4 - Hongchun Zhang.
Author 5 - Bang Yu.

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