INPLASY PROTOCOL

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None declared.

Yiqi Wenyang Huoxue Method in Treating Stable Chronic Obstructive Pulmonary Disease: A Systematic Review and Meta-Analysis

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Review question / Objective: **This research aimed to assess the efficacy and safety on the YQWYHXM combined with western medicine(WM) for COPD**
Condition being studied: **Chronic obstructive pulmonary disease (COPD) is a progressive disease with complex pathogenesis, which can gradually evolve into pulmonary heart disease and even death unless treated actively and promptly, but its treatment is fairly tricky.**
Information sources: **Randomized controlled studies of YQWYHX combined with WM in stable COPD by PubMed, EMBASE, The Cochrane Library, CNKI, Wanfang, and VIP databases were retrieved, which were not restricted by race or language.Besides, pivotal reference lists on connected studies would also be identified by Manual retrieves to avoid missing any qualified literature.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 August 2022 and was last updated on 03 August 2022 (registration number INPLASY202280011).

INTRODUCTION

Review question / Objective: **This research aimed to assess the efficacy and safety on the YQWYHXM combined with western medicine(WM) for COPD**

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METHODS

Participant or population: The subjects of all studies were patients with a defined diagnosis of stable COPD. The diagnostic criteria refer to the "Guidelines for the Diagnosis and Treatment of Chronic Obstructive Pulmonary Disease "formulated by the Chinese Medical Association. Moreover, all included studies explicitly appeared the description of "stable period" or "remission period".

Intervention: For YQWYHX (not limited to decoction, capsule, and pill) on the basis of Western medicine.

Comparator: For western medicine alone (Salmeterol/Fluticasone, theophylline, Tiotropium Bromide, salbutamol),

Study designs to be included: Clinical randomized controlled studies were conducted on the treatment of stable COPD with YQWYHX plus WM(non-blind design is not excluded).

Eligibility criteria: Exclusion criteria(1)Review, animal experiments, and case reports(2)Combined with other types of diseases(3) The full text of the study couldn't be obtained;(4)Duplicate publications. The latest one was selected for the research with the repeated publication or repeated data.

Information sources: randomized controlled studies of YQWYHX combined with WM in stable COPD by PubMed, EMBASE, The Cochrane Library, CNKI, Wanfang, and VIP databases were retrieved, which were not restricted by race or language.Besides, pivotal reference lists on connected studies would also be identified by Manual retrieves to avoid missing any qualified literature.

Main outcome(s): Pulmonary functions such as Forced vital capacity(FVC), FEV1/ predicted value (FEV1%); St. George's Respiratory Questionnaire (SGRQ);6-minute walking test(6MWT); the number of acute exacerbations; clinical effective rate; adverse events; Inflammatory indicators such as Tumor Necrosis Factor α (TNF-α), interleukin-6.

Quality assessment / Risk of bias analysis: The evaluation of literature quality was carried out by two researchers(Rongfang Xie and Miaomiao Li) using the RCT bias risk assessment tool recommended in Cochrane manual 5.4.0. The risk of bias assessment mainly revolves around seven aspects:(1)random design, (2)whether the allocation to hide, (3)whether the patients and personnel were blinding,(4)the blinding implementation of outcome evaluation,(5) incomplete outcome data, (6) selective reporting, (7) other potential sources of bias.

Strategy of data synthesis: Review Manager 5.4.2 and stata16.0 statistical software were used for meta-analysis. The Binary variables were analyzed by odds ratio(OR) and 95% confidence interval (95%CI). For analysis of continuous variables, mean difference (MD) and 95%CI would be employed when measurement units were of the same, otherwise used standardized mean difference (SMD) and 95%CI; Heterogeneity between studies was determined by quantitative analysis of the I2 test. The fixed-effects model with slight homogeneity (P>0. 1, I2.

Subgroup analysis: subgroup analysis was required to discuss the causes of heterogeneity.

Sensitivity analysis: Additionally, we took sensitivity analysis to judge the stability of each outcome.

Country(ies) involved: China.

Keywords: YQWYHXM; TCM; stable COPD; meta-analysis.

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