INPLASY PROTOCOL

To cite: Yue et al. The effectiveness of Du moxibustion for chronic obstructive pulmonary disease A protocol for systematic review and meta-analysis of randomized clinical trials. Inplasy protocol 202110045. doi: 10.37766/inplasy2021.1.0045

Received: 13 January 2021

Published: 14 January 2021

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Support: **Jiangxi University.**

Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
The authors report no conflicts of interest to disclose.

The effectiveness of Du moxibustion for chronic obstructive pulmonary disease A protocol for systematic review and meta-analysis of randomized clinical trials

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Review question / Objective: **This research mainly evaluated the efficacy and safety of Du moxibustion in the treatment of COPD.**
Condition being studied: **As a common respiratory disease, Chronic Obstructive Pulmonary Disease (COPD) develops progressively. Du moxibustion can effectively treat COPD, and no adverse reactions have been reported.**
Information sources: **Seven databases (PubMed, Embase, Cochrane Library, China National Knowledge Infrastructure (CNKI), Chinese Biomedical Literatures Database (CBM), Wanfang Database (WF), Chinese Scientific Journal Database (VIP) will be searched. WHO international registry center of clinical trials and the Chinese clinical trial registry center also need to be searched to ensure that the literature can be as comprehensive as possible.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 January 2021 and was last updated on 14 January 2021 (registration number INPLASY202110045).

INTRODUCTION

Review question / Objective: **This research mainly evaluated the efficacy and safety of Du moxibustion in the treatment of COPD.**

Condition being studied: **As a common respiratory disease, Chronic Obstructive Pulmonary Disease (COPD) develops progressively. Du moxibustion can**

effectively treat COPD, and no adverse reactions have been reported.

METHODS

Participant or population: COPD patients included in this study need to be diagnosed first.

Intervention: The observation group can be treated with single Du moxibustion or combined with other therapies, such as western medicine, traditional Chinese medicine, needling, etc.

Comparator: The treatment of the control group can use simple western medicine, Chinese medicine, placebo, other therapies or no treatment.

Study designs to be included: All clinical randomized controlled trials (RCTs) of Du moxibustion in the treatment of COPD will be selected.

Eligibility criteria: No matter what type of COPD patients were diagnosed, they could be included regardless of gender, age, nationality or education background. Those people allergic to moxibustion, intolerant of moxa smoke, or those with ulcers at the moxibustion site should be excluded.

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Main outcome(s): The main results included clinical efficacy, clinical symptoms of COPD and changes of pulmonary function indexes.

Additional outcome(s): Other results include the following: (1) Six minute walk test (6MWT). (2) Blood gas analysis indexes: PaO2, PaCO2, SaO2. (3) The levels of serum CRP, IL-8, and T cells (CD4+, CD8+) were measured.

Quality assessment / Risk of bias analysis: We will apply the Cochrane risk of bias tool to evaluate the quality of the included studies. It mainly includes the following items: whether the grouping scheme is really random, the allocation scheme is hidden, the blind method is used in the research process, the inclusion criteria are detailed, the baseline between groups is comparable, the outcome data is complete, and other possible bias risks. According to the evaluation, the results can be divided into three categories: risk of high bias, risk of low bias or risk of unclear bias. When there exist differences, we will ask the third author to make a ruling.

Strategy of data synthesis: We will select models according to the data type. If the data is binary, the odds ratio will be used; if the data is continuous, the normalized mean difference will be used. According to the heterogeneity test results of this research, fixed or random effect models will be selected.

Subgroup analysis: Once we find high heterogeneity in the above heterogeneity test, we will analyze the data according to the TCM syndrome differentiation of COPD and the intervention methods of the control group.

Sensibility analysis: If the heterogeneity is high, we need to exclude low-quality, small sample studies and then conduct a Meta-analysis again to compare the results with the results of the non-exclusion Meta-analysis. On if the result does not substantially change any more, can it be viewed as credible. On the contrary, we should be very careful in explaining the results and drawing conclusions.

Country(ies) involved: China.

Keywords: Du moxibustion; chronic obstructive pulmonary disease; protocol; systematic review.

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