## INPLASY PROTOCOL

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**Review Stage at time of this submission:** The review has not yet started.

Conflicts of interest: None declared. Efficacy and safety of cupping combined with Chinese herbal medicine in the treatment of asthma: A protocol for systematic review and meta-analysis

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**Review question / Objective:** "The aim of this systematic review is to compare cupping combined with Chinese herbal medicine and best supportive treatment in terms of efficacy and acceptability in the asthma to better inform clinical practice. To this end, the proposed systematic review will address the following question: Which is the best choice to reduce PEF, FVC, and FEV1, in asthma patients, cupping combined with Chinese herbal medicine or best supportive treatment ?".

Information sources: The protocol was prepared based on the preferred reporting project of the systematic review and meta-analysis protocol statement guidelines. Our research does not require ethical approval, as all analyses will be based on aggregated data from previously published studies. We will search the following Chinese and English databases: the China National Knowledge Infrastructure, Chinese Scientific Journal Database, Wanfang Database, China Doctoral Dissertations Full-Text Database, China Master's Theses Full-Text Database, Cochrane Central Register of Controlled Trials, PubMed, and Embase. All of the above electronic databases will be searched from inception to August 22, 2021. In addition, we will manually search for conference papers, ongoing experiments and internal reports to supplement the studies retrieved via electronic search.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 September 2021 and was last updated on 25 September 2021 (registration number INPLASY202190089).

## INTRODUCTION

Review question / Objective: "The aim of this systematic review is to compare

cupping combined with Chinese herbal medicine and best supportive treatment in terms of efficacy and acceptability in the asthma to better inform clinical practice. To this end, the proposed systematic review will address the following question: Which is the best choice to reduce PEF, FVC, and FEV1, in asthma patients, cupping combined with Chinese herbal medicine or best supportive treatment ?".

Condition being studied: Asthma is one of the most common chronic airway diseases and is characterized by wheezing, dyspnea, chest tightness and coughing [1]. These symptoms reduce the patient's quality of life and limit physical activity in daily life [2]. At present, approximately 334 million people worldwide suffer from asthma, and its incidence is increasing rapidly at a rate of 20%-25% every ten years. It is estimated that the number of asthma patients will increase to 400 million in 2025, which will lead to a huge health and economic burden in the country [3]. Corticosteroids are conventional drugs for the treatment of bronchial asthma. However, despite the use of medium to high doses of inhaled corticosteroids and long-acting ß2 receptor agonists, many patients with severe asthma continue to experience asthma symptoms and worsening, leading to the emergence of refractory asthma [4]. In addition, the long-term use of steroid drugs will bring about a series of adverse reactions, such as local Candida infection. cataracts, glaucoma, osteoporosis, tachycardia, and hyperglycemia [5]. Existing studies have shown that cupping therapy can quickly improve the symptoms of asthma patients who are not sensitive to corticosteroids and bronchodilators and can be used as an alternative therapy [6]. Traditional Chinese medicine (TCM) is an effective therapy of complementary and alternative medicine. More and more scientific evidences support the use of TCM for asthma treatment, and active ingredients from Chinese medicine plants are becoming a hot issue [7]. However, there is no systematic review of the efficacy of cupping combined with Chinese herbal medicine (CHM) in the treatment of asthma. To evaluate the efficacy and safety of cupping combined with CHM in the treatment of asthma, we conducted a systematic review and meta-analysis of published randomized clinical trials (RCTs)

of cupping combined with CHM in the treatment of asthma. We aim to provide a scientific reference plan for the alternative treatment of asthma.

## **METHODS**

Search strategy: We will use "cupping", "Chinese herbal medicine" and "asthma" as keywords to retrieve RCTs examining the treatment of asthma. All of the above electronic databases will be searched from inception to August 22, 2021. In addition, we will manually search for conference papers, ongoing experiments and internal reports to supplement the studies retrieved via electronic search.

Participant or population: Asthma patients will be eligible for this review, with no exclusions based on ethnicity, gender or age.

**Intervention:** The treatment group was treated with cupping combined with CHM.

**Comparator:** The control group was treated with the best supportive treatment.

Study designs to be included: Randomized controlled trial.

Eligibility criteria: The inclusion criteria will be as follows: meeting the clinical diagnostic criteria for asthma, regardless of race, age and gender; All randomized controlled trials of asthma in Chinese and English versions since the establishment of the database; The treatment group was treated with cupping combined with CHM, and the control group was treated with the best supportive treatment. research articles that evaluate the maximum peak expiratory flow rate (PEF), forced vital capacity (FVC), forced expiratory volume in the first second (FEV1), asthma control questionnaire (ACQ) score, and asthma quality of life questionnaire (AQLQ) score. The exclusion criteria will be as follows: studies that do not meet the above inclusion criteria; incomplete or incorrectly researched data; patients with asthma who have other diseases or serious complications; case reports, comments or letters, biochemical tests, protocols, meeting abstracts and reviews.

Information sources: The protocol was prepared based on the preferred reporting project of the systematic review and metaanalysis protocol statement guidelines. Our research does not require ethical approval, as all analyses will be based on aggregated data from previously published studies. We will search the following Chinese and English databases: the China National Knowledge Infrastructure, Chinese Scientific Journal Database, Wanfang Database, China Doctoral Dissertations Full-Text Database, China Master's Theses Full-Text Database, Cochrane Central Register of Controlled Trials, PubMed, and Embase. All of the above electronic databases will be searched from inception to August 22, 2021. In addition, we will manually search for conference papers, ongoing experiments and internal reports to supplement the studies retrieved via electronic search.

Main outcome(s): The main outcome indicators will be PEF, FVC, and FEV1.

Additional outcome(s): The secondary outcome indicators will include ACQ score, AQLQ score and adverse events.

Data management: The literature will be independently screened by two researchers (XW and XD) according to the inclusion and exclusion criteria. Then, the data extracted by each researcher will be given to the other party for inspection, and any disagreements will be resolved via discussion. The researchers will first read the titles and abstracts, conduct a preliminary screening, and exclude articles that are not related to the research topic. Then, they will read the full text further to determine whether a study can be included. Literature screening process: Endnote software will be used to eliminate duplicate literature; the title and abstract of the articles will be read, and irrelevant literature will be excluded; the full text of the remaining articles will be read to determine whether these studies will be included in the study.

Quality assessment / Risk of bias analysis: Two researchers (YH and JW) will use the RCT bias risk assessment tool recommended by the Cochrane Collaboration Network bias risk assessment tool to assess the risk of bias a mong the included studies. Disagreements will be resolved by consulting a third researcher.

Strategy of data synthesis: We will use RevMan 5.4 software for the meta-analysis. We will use relative risk as an effective indicator of counting data and use the mean differences as an effective indicator of measurement data. The confidence interval for each effect index will be set to 95%. Additionally, 12 will be used to quantitatively assess heterogeneity. If there is no statistical heterogeneity between the studies, a fixed effects model will be used for the meta-analysis. If there is heterogeneity, a random effects model will be used. P <0.05 indicates statistical significance.

Subgroup analysis: When there is potential heterogeneity in this study, if all the information included in the study was available, we could perform subgroup analysis based on the sex, age and treatment time of the included subjects.

Sensitivity analysis: A sensitivity analysis will be performed to assess the robustness of the included results. If the results are unstable, studies with a high risk of bias will be excluded.

Language: None limitation.

Country(ies) involved: China.

Keywords: cupping, Chinese herbal medicine, asthma, protocol, systematic review.

**Dissemination plans:** We plan to submit this systematic review to a peer-reviewed journal.

## **Contributions of each author:**

Author 1 - Lei Guo - The author participates in conception evaluation, design

evaluation, coordination evaluation, data collection, data management, data analysis, interpretation of data and preparation of scheme.

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Author 2 - Lie Wang - The author participates in conception evaluation, design evaluation, preparation evaluation and financial support.

Author 3 - Zhongtian Wang - The author participates in conception evaluation, design evaluation, data management and scheme writing.

Author 4 - Lina Wei - The author participates in conception evaluation, coordination evaluation, data collection, data analysis, data interpretation and scheme preparation.

Author 5 - Lizhong Ding - The author is involved in conceptualizing evaluations, coordinating evaluations, data collection, interpreting data and writing programs.

Author 6 - Yibu Kong - The author participates in design evaluation, coordination evaluation, interpretation of data and preparation of schemes.

Author 7 - Zhimei Liu - The author participates in design evaluation, coordination evaluation, interpretation of data and preparation of schemes.

Author 8 - Ye Tian - The author is involved in data collection, data management, data analysis and interpretation.

Author 9 - Fushuang Yang - The author is involved in data collection, data management, data analysis and interpretation.

Author 10 - Liping Sun - The author participates in conception evaluation, design evaluation, preparation evaluation and financial support.