INPLASY PROTOCOL

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

Conflicts of interest:
None.

A comparison of efficacy and safety of complementary and alternative therapies for children with asthma - A protocol for systematic review and meta analysis

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Review question / Objective: **Bronchial Asthma is a chronic, hyperreactive inflammation of the airway that involves a variety of inflammatory cells. Due to the persistence of airway hyperresponsiveness, lung function is progressively damaged, making asthma more stubborn and difficult to heal. In recent years, the prevalence of childhood asthma is still on an increasing trend. Repeated asthma attacks not only affect children's life and learning, but also bring greater economic and mental burden to children's families, and even threaten children's lives. Traditional treatment methods such as oral western medicine, atomization therapy has obvious limitations, and the complementary and alternative therapy is an effective method to treat asthma in children. This study will evaluate the efficacy and safety of various complementary and alternative therapies for children with asthma by means of mesh meta-analysis. In order to provide the basis for clinical rational use.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 February 2021 and was last updated on 01 February 2021 (registration number INPLASY202120005).

INTRODUCTION

Review question / Objective: **Bronchial Asthma is a chronic, hyperreactive inflammation of the airway that involves a variety of inflammatory cells. Due to the persistence of airway hyperresponsiveness, lung function is progressively damaged, making asthma more stubborn and difficult to heal. In recent years, the prevalence of childhood asthma is still on an increasing trend. Repeated asthma attacks not only affect children's life and learning, but also bring greater economic and mental burden to children's families, and even threaten children's lives. Traditional treatment methods such as oral western medicine,**

atomization therapy has obvious limitations, and the complementary and alternative therapy is an effective method to treat asthma in children. This study will evaluate the efficacy and safety of various complementary and alternative therapies for children with asthma by means of mesh meta-analysis. In order to provide the basis for clinical rational use.

Condition being studied: Use the computer to search the self-built database until January 2021, the China National Knowledge Infrastructure (CNKI), Wanfang Database, Chinese Scientific Journals Database (VIP), China Biomedical Literature Database (CBM), PubMed, Cochrance Library, EMBASE, Web of Science, Clinical Trials and other electronic databases to collect RCT studies on complementary and alternative therapies for for children with asthma. We will screen the relevant literature included in the systematic review/meta analysis. At the same time, Revman 5.3 software will be used for meta-analysis, and grade will be used to grade the quality of evidence in the network meta-analysis (NMA).

METHODS

Participant or population: Meet the relevant diagnostic criteria for bronchial asthma in children, and the severity of the illness is unlimited. The age is between 1 and 18 years old. There are no restrictions on gender and race.

Intervention: In the treatment group, basic intervention measures were adopted, including moxibustion, massage, traditional Chinese medicine, acupoint application and other complementary and alternative therapies, on the basis of conventional treatment in western medicine. Different interventions can be used individually or in combination.

Comparator: The control group received conventional western medicine treatment.

Study designs to be included: Randomized controlled trials (RCTs), whether to use blind method, and systematic review / meta-analysis of complementary and alternative therapies for childhood asthma, including moxibustion, massage, Chinese herbal medicine, acupoint application, etc.

Eligibility criteria: Binary variables were expressed by Odds Ratio (OR), continuous variables were expressed by Mean Difference (MD), and 95% Confidence Interval (CI) was used for interval estimation, with $P < 0.05$ as the difference was statistically significant. If $P > 0.5$ and $I2 < 50\%$ between the results of each study, then there is no statistical heterogeneity among the studies, and the results will be meta-analyzed using a fixed-effect model. If $P \leq 0.5$ and $I2 \geq 50\%$ between the research results, it indicates that there is heterogeneity, analyze the causes of heterogeneity, conduct subgroup analysis, and use fixed effect model for analysis. Also need to rule out obvious clinical heterogeneity. If the heterogeneity comes from a low-quality study, a sensitivity analysis of the results is performed.

Information sources: The general search principle is based on subject terms and free words, and the search time limit is from the date of establishment of each database to January 2021. Computer search of electronic databases such as China Knowledge Network (CNKI), Wanfang Database, Chinese Science Journal Database (VIP), China Biomedical Literature Database (CBM), PubMed, Cochrance Library, EMBASE, Web of Science, Clinical Trials, etc, to collect relevant information RCT study of complementary and alternative treatments for childhood asthma.

Main outcome(s): Outcome indicators: (1) The effective rate standard is based on the efficacy index (that is, the difference between the scores before and after treatment/the percentage of the score before treatment). Healing is curative index>90%, markedly effective is curative index 61%~90%, effective is curative index 30%~60%, and invalid is curative index<30%. In addition, the outcome indicators also include disease recurrence rate, incidence of adverse reactions and so

on; (2) Pulmonary function indicators: forced expiratory volume at the end of the first second (FEV1), forced vital capacity (FVC), forced expiratory volume at the end of the first second, percentage of forced vital capacity (FEV1/FVC); (3) The occurrence of adverse reactions.

Quality assessment / Risk of bias analysis: Evaluate the risk of bias in selected documents according to Cochrance Handanbook 5.1 evaluation criteria items and tools. Independent evaluation by 2 evaluators, cross-check after the completion of the evaluation, if there is a difference, it needs to be negotiated. The evaluation items are: (1) Generation of random sequence; (2) Allocation hiding; (3) Implementation of blind method for researchers and subjects; (4) Implementation of blind method for evaluation of outcome indicators; (5) Complete result data Sex; (6) Selective reporting of research results; (7) Other sources of bias. The above items are evaluated as "high", "low" and "unclear".

Strategy of data synthesis: The Rev Man 5.3 software provided by Cochrane Collaboration was used for statistical analysis. Binary variables were expressed by Odds Ratio (OR), continuous variables were expressed by Mean Difference (MD), and 95% Confidence Interval (CI) was used for interval estimation, with $P < 0.05$ as the difference was statistically significant. If $P > 0.5$ and $I2 < 50\%$ between the results of each study, then there is no statistical heterogeneity among the studies, and the results will be meta-analyzed using a fixed-effect model. If $P \leq 0.5$ and $I2 \geq 50\%$ between the research results, the random effects model will be used for meta-analysis. Also need to rule out obvious clinical heterogeneity. If the heterogeneity comes from a low-quality study, a sensitivity analysis of the results is performed.

Subgroup analysis: If $P \leq 0.5$ and $I2 \geq 50\%$ between the research results, it indicates that there is heterogeneity, analyze the causes of heterogeneity, conduct subgroup analysis, and use fixed effect model for analysis.

Sensitivity analysis: If the heterogeneity comes from a low-quality study, a sensitivity analysis of the results is performed.

Language: No restriction.

Country(ies) involved: China.

Keywords: children with asthma; net meta-analysis; complementary and alternative therapy; protocol; systematic review.

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