INPLASY PROTOCOL

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Support: None.

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Efficacy and safety of Tuina for treatment of pediatric recurrent respiratory tract infections: A protocol for systematic review and meta-analysis

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Review question / Objective: The purpose of this study will be to evaluate the efficacy and safety of Tuina massage for the treatment of pediatric patients who experience RRTIs.

Condition being studied: Recurrent respiratory tract infections (RRTIs) are common respiratory ailments in children. RRTIs are often difficult to control and thus generally have a long-term disease course. Children who receive ineffective treatments or those that experience poor treatment outcomes are prone to developing complications such as edema, cough and asthma. Such complications can seriously hinder a child's growth and development, while also adversely affecting the child's physical and mental health. Tuina massage, a traditional Chinese technique that has been practiced in China for over 5000 years, has recently been used to treat RRTIs, with good effect. However, no systematic review of research studies focusing on massage as a treatment for RRTIs can be found in the literature to date.

INTRODUCTION

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METHODS

Search strategy: We will search the following databases using electronic methods: the Chinese Biomedical Literature Database (CBM), the China National Knowledge Infrastructure (CNKI), Wanfang Data (WAN FANG), VIP Information (VIP), MEDLINE, PUBMED, EMBASE and CINAHL. For each database search, the scope will include papers published between the date of database inception to September 2021. Revman5.4 software will be used to conduct this systematic review and meta-analysis.

Participant or population: Children with recurrent respiratory tract infections were not excluded based on race or age.

Intervention: Pediatric massage, unlimited manipulation.

Comparator: Control measures: blank control, or any standard drug control supported by previous evidence, such as pidotimod, spleen aminopeptide oral lyophilized powder or supplement containing trace elements and multivitamins. Studies of pediatric massage combined with other treatments and homeotherapies were also included.

Study designs to be included: RCT.

Eligibility criteria: Pediatric patients with clear TTRI diagnosis. Only randomized controlled trials (RCTs) published or registered before September 1, 2021 are included.

Information sources: the Chinese Biomedical Literature Database (CBM), the China National Knowledge Infrastructure (CNKI), Wanfang Data (WAN FANG), VIP Information (VIP), MEDLINE, PUBMED, EMBASE and CINAHL.

Main outcome(s): Primary prognostic indicators (outcomes) included curative effect and the number of episodes of respiratory tract infection.

Additional outcome(s): secondary prognostic markers included levels of immunoglobulin (IgA, IgG, IgM) and T lymphocytes (CD3+, CD4+, CD8+, CD4+/CD8+).

Quality assessment / Risk of bias analysis: The Cochrane bias risk assessment tool [14] will be used to evaluate the quality of the methodology used to search the literature. Because the subjects of this study are children under 18 years of age, main outcome indicators will include curative effect and frequency of respiratory tract infections, while immunoglobulin levels and T lymphocyte levels will serve as relative objective indicators. We think that implementation of a blinded method would have little effect on the outcome, since the intervention under evaluation in this meta-analysis is a non-drug-based therapy, making implementation of a placebo-controlled blinded study difficult. Thus, the term "blind method for study subjects" was removed from the original set of seven search terms. Quality evaluation results for each item will be divided into three grades: "low bias risk," "high bias risk" and "bias risk uncertainty."

Strategy of data synthesis: Data will be subjected to statistical analysis using RevMan5.4 software. First, the results of a single study will be described. Next, relative risk (RR) and its 95% confidence interval (CI) will be used as dichotomous outcome variables of massage safety and efficacy; the mean difference (MD) and its 95%CI will be used as continuous variables to describe massage effects as numerical values derived from inter-group comparisons. To assess clinical

heterogeneity between studies, clinical heterogeneity of study subjects, intervention measures, control measures and outcome indicators each will be assessed for similarities among the different studies. To assess statistical heterogeneity between studies, statistical heterogeneity will be judged according to the results of the I2 test; if I2 > 75%, the statistical heterogeneity between studies is very significant but does not meet the level of significance required for meta-analysis studies; 25% ≤ I2 ≤ 75% indicates that clinical homogeneity is better than that mentioned above based on a random effect model; when I2 < 25%, a fixed effect model is used.

Subgroup analysis: For robust data, subgroup analysis will be conducted using several different types of controls to control for "different pediatric massage techniques" and "different courses of treatment". Next, the stability of the results will be judged using sensitivity analysis (only high-quality studies will be compared with the combined results of all studies).

Sensitivity analysis: Wherever possible, we will conduct sensitivity analysis to explore the impact of bias risk of a trial on the preliminary results. These analyses will exclude lower-quality trials, duplicates of meta-analysis papers, studies with insufficient sample size and/or insufficient data for assessing data quality and robustness when significant statistical heterogeneity is found.

Country(ies) involved: China.

Keywords: Tuina; meta-analysis; recurrent respiratory tract infections.

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