INPLASY PROTOCOL

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There is no conflicts of intrest.

Pediatric tuina for the treatment of fever in children: a protocol for systematic review and meta-analysis

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Review question / Objective: **(PICOS strategy) Population (P): Participants are younger than or equal to 14 years old, male or female, and they will comply with authoritative clinical diagnostic standards for pediatric fever, excluding that suffer from other serious illnesses, such as diseases in heart, liver, kidney and blood system , infectious diseases and severe hereditary diseases, without symptoms such as dizziness, convulsions and so on. Interventions (I): Children of the intervention group should receive tuina alone or combined with integrative medicine or other conventional medicine. There will be no limitations about the type of manipulation (acupoint massage, abdominal massage, spinal pinching), time and treatment course of tuina. Control (C): Children of the control group should receive other routine treatments, such as phototherapy, drug therapy, touch therapy, observation and nursing. Outcome (O): The significant effective rate will be used to the primary outcome, which is defined as the abatement of fever in a special period of time (meet the effective standards of pediatric febrile disease). Secondary outcomes will include the occurrence of adverse events. Study design (S): randomized controlled experiment (RCT).**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 June 2020 and was last updated on 10 June 2020 (registration number INPLASY202060032).

INTRODUCTION

Review question / Objective: **(PICOS strategy) Population (P): Participants are younger than or equal to 14 years old, male or female, and they will comply with authoritative clinical diagnostic standards for pediatric fever, excluding that suffer from other serious illnesses, such as diseases in heart, liver, kidney and blood system , infectious diseases and severe hereditary diseases, without symptoms such as dizziness, convulsions and so on. Interventions (I): Children of the intervention group should receive tuina alone or combined with integrative**

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Condition being studied: Pediatric fever is a common pediatric disease, which is often caused by colds, food accumulation or other factors, in which exogenous fever accounts for the chief reason in pediatric diseases. Persistent high fever may cause febrile convulsions and even brain cell damage in children. Western medicine believes that fever is caused by a series of reactions caused by internal antigen-antibody complexes or external bacteria, viruses, fungi, spirochetes, etc., and oral ibuprofen and acetaminophen are often given in clinic. It has a certain curative effect, but the side effects can not be avoided. Pediatric tuina is regarded as an acceptable non-pharmaceutical therapy for children with positive effects on pediatric disease treatment and health care, which has been widely used in China. According to clinical observation, it can treat pediatric fever caused by external or internal reasons , which can be used alone or in combination with traditional Chinese medicine and acupuncture to achieve antipyretic effect. However, there is still a lack of systematic evaluation and research on the safety and effectiveness of pediatric tuina for the treatment of fever in children.

METHODS

Participant or population: Inclusion criteria: Participants should meet the following eligibility criteria: 1 - Patients are younger or equal to 14 years old, male or female. 2 - Comply with authoritative clinical diagnostic standards for pediatric fever. 3 - Within 48 hours after the onset, without fever treatment or self-administered drugs are ineffective. 4 - Children receive Tuina alone or combined with integrative medicine or other conventional medicine. There would be no limitations about the type of manipulation, acupuncture points, time and treatment course of Tuina; 5 - Children receive other routine treatments, such as phototherapy, drug therapy, touch therapy, observation and nursing; Exclusion criteria: Children with fever suffering from other serious illnesses, such as diseases in heart, liver, kidney and blood system, infectious diseases and severe hereditary diseases without symptoms such as dizziness, convulsions and so on.

Intervention: Patients of the intervention group should receive Tuina alone or combined with integrative medicine or other conventional medicine. There would be no limitation about the type of manipulation (acupoint massage, abdominal massage, spinal pinching), time and treatment course of Tuina.

Comparator: Patients of the control group should receive other routine treatments, such as phototherapy, drug therapy, touch therapy, observation and nursing.

Study designs to be included: Inclusion criteria: All randomized controlled trials (RCTs) that have published and can be obtained with the languages of English and Chinese.

Eligibility criteria: Inclusion criteria: All randomized controlled trials (RCTs) that have published and can be obtained with the languages of English and Chinese. Exclusion criteria: 1 - the full paper cannot be obtained, the data cannot be extracted completely and duplicate studies; 2 - the studies which are published as a letter, review, abstract or conference poster.

Information sources: We will search for the studies in Cochrane Library , EMBASE, Pubmed, China National Knowledge Infrastructure (CNKI), Wanfang Database

and VIP Database, the language of studies will be limited in English and Chinese. If the data are unreported, we will try to contact the authors to request the original data, when those are necessary for the completion of the systematic review. what's more, if the studies which are published as a letter, reviews, abstract or conference poster will be excluded unless sufficient data can be acquired from the authors.

Main outcome(s): The significant effective rate will be used to the primary outcome, which is defined as the abatement of fever in a special period of time (meet the effective standards of pediatric febrile disease). Significant effective rate = (the number of significant effective participants / total number of participants) × 100%.

Additional outcome(s): Secondary outcomes will include the occurrence of adverse events.

Quality assessment / Risk of bias analysis: Two reviewers will evaluate the included RCTs' risk of bias independently, which are in terms of selection bias (random sequence generation, allocation concealment), performance bias(blinding of participants and personnel, blinding of outcome assessment), attrition bias(incomplete outcome data), reporting bias(selective reporting)and other bias. "high risk", "low risk" or "unclear risk" will be used to determine the result above. Disparities will be resolved by discussion and consultation with other authors in our group and then made a judgment by basing on consensus.

Strategy of data synthesis: We will record dichotomous outcomes of participants experiencing in the studies, extract the standard deviations and means of the continuous outcomes, enter the information into RevMan 5.3. We will use risk ratio(RR) with 95% confidence intervals (CI) to summarize the dichotomous data, and use standardized mean difference(SMD) with 95% CI to summarize continuous outcomes. What's more, using Cochrane's Q test to assesse the existence of heterogeneity and the extent of the heterogeneity will be quantified using the I2 statistics (large heterogeneity 50%–69%; very large heterogeneity >70%). If non-significant heterogeneity is found among pooled studies, we will use a fixed effect model to summarise the results of the studies; if the heterogeneity is found, we will use the subgroup analysis, divide all the data into smaller units and compare them within each subgroup. If the trials had a similar clinical characteristics (on study design, control, interventions, participants, and outcome measures) and acceptable statistical heterogeneity, we will carry out the meta-analysis. If there is a great heterogeneity within the studies (I2 >70%), we will conduct a narrative synthesis by the available data.

Subgroup analysis: We will use subgroup analysis to explore the sources of heterogeneity in the different diagnosis reasons (colds, food accumulation and so on), and different intervention types (using a kind of treatment alone or combining with other treatments).

Sensibility analysis: We will use the iteratively removing one study at a time of ReveMan5.3 to finish the sensitivity analysis.

Country(ies) involved: China.

Keywords: Pediatric tuina; Fever; Children; Intervention, Systematic review, Meta-analysis.

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