

# INPLASY PROTOCOL

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There is no conflicts of interest.

## 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 04 July 2020 (registration number INPLASY202060032).

### INTRODUCTION

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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).

**Condition being studied:** Pediatric fever is a common symptom of the pediatric diseases, accounting for 30% of pediatric emergencies. It is often caused by upper respiratory tract infection, pneumonia, diarrhea, indigestion and other factors. It is generally believed that fever is a defense response by the body to fight against and eliminate germs. However, long-lasting high fever can lead to abnormal regulation of various organs and tissues in children's body, even seriously lead to convulsions, destroy brain tissue, leave irreversible sequelae, and bring harm to children's health. 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. Therefore, oral ibuprofen and acetaminophen are often given in clinic. It has a certain curative effect, but the side effects are unavoidable. So parents are looking for greener antipyretic methods. Pediatric tuina is regarded as an acceptable non-pharmacotherapy for children with positive effects on pediatric disease, which has been widely used in China. Pediatric tuina is a characteristic therapy in the treatment of diseases by hand manipulation, such as pushing, grasping, kneading, rubbing and so on. Under the guidance of the theoretical basis of syndrome differentiation and treatment of traditional Chinese medicine, special parts of children's body (mostly acupoints) are

selected to achieve the purpose of tonifying deficiency and purging excess, adjusting yin and yang, relaxing muscles and dredging collaterals, promoting qi and activating blood circulation. From the clinical observation, pediatric tuina is suitable for fever caused by different reasons, which can be used alone or combined with other treatments, such as traditional Chinese medicine, acupuncture, scraping, cupping and so on. Although pediatric tuina is popular, there is still a lack of high-quality clinical evidence to prove the safety and effectiveness of pediatric tuina in the treatment of infantile febrile disorders.

## METHODS

**Participant or population:** The age of participants is 14 years or under, male or female, They will comply with authoritative clinical diagnostic standards for pediatric fever, excluding those suffer from other serious illnesses, such as the diseases in heart, liver, kidney and blood system, infectious diseases and severe hereditary diseases, without symptoms such as dizziness, convulsions and so on.

**Intervention:** Children 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 tuina manipulation (acupoint tuina, abdominal tuina, 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, WHO International Clinical Trials Registry Platform (WHOICTRP), Web of Science, China National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM), Wanfang Database and VIP Database. The language of studies will be limited to 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 as the primary outcome, which is defined as the abatement of fever in a special period of time (meet the authoritative clinical effective standards for pediatric fever). Significant effective rate = (the number of significant effective participants / total number of participants) × 100%. Secondary outcomes will include the occurrence of adverse events.

**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 assess the existence of heterogeneity and the extent of the heterogeneity will be quantified using the I<sup>2</sup> 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 summarize 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 (I<sup>2</sup> >70%), we will conduct a narrative synthesis by the available data.

**Subgroup analysis:** If the included studies have a high heterogeneity, we will use the subgroup analysis to explore the sources of heterogeneity in the different diagnosis reasons (exogenous pathogenic factors, indigestion and so on), and different intervention types (only one kind of therapy or combining with other therapies).

**Sensitivity analysis:** If the quality of studies is low, or the outliers that are numerically distant from the rest of the data, a sensitivity analysis will be required. We will use the iteratively removing one study at a time of RevMan 5.3 to finish the sensitivity analysis.

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**Country(ies) involved:** China.

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

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