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**Author Affiliation:**The First Affiliated Hospital of  
Nanchang University.**ADMINISTRATIVE INFORMATION****Support** - 1050Project: 5141900101.**Review Stage at time of this submission** - The review has not yet started.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202370096**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 July 2023 and was last updated on 23 July 2023.**INTRODUCTION**

**Review question / Objective** This review in order to summarize the available evidence from randomized controlled trial for the efficacy of Tuina therapy for infantile diarrhea.

**Condition being studied** Infantile diarrhea is a clinical syndrome caused by multiple pathogens and factors, which is characterized by the increased number of stools and changes in the characteristics of stools. Infantile diarrhea in children is common in infants and young children, with a high incidence of disease. The main cause is the incomplete development of physical function in children, excessive diet, and improper feeding, resulting in the weakness of the spleen and stomach in children, resulting in a significant decline in digestive function. Because the food was not digested, the child showed increased stool frequency, abdominal distension, diarrhea, and loss of appetite. When children maintain diarrhea for a long time, it will cause indigestion and various nutrition-related diseases, which will

affect the growth of children. Apart from it, a prolonged diarrhea may cause serious consequences and may severely affect the health status of the children.

Tuina therapy in traditional Chinese medicine has been widely used in many diseases, and the efficacy of Tuina therapy in treating infantile diarrhea has been reported in some studies. However, the efficacy of Tuina therapy in the treatment of infantile diarrhea lacks high-level evidence-based medical support. This study aimed to systematically evaluate the clinical value of Tuina therapy in patients with infantile diarrhea.

**METHODS**

**Participant or population** Patients with infantile diarrhea.

**Intervention** Tuina or any combination of the above.

**Comparator** Placebo can be used for various effective conventional Western medicine,

acupuncture treatment or other traditional Chinese medicine treatments, or any combination of these. Western medicine, placebo, acupuncture, no treatment, or any combination of these.

**Study designs to be included** All randomized controlled trial on the use of Tuina therapy for infantile diarrhea.

**Eligibility criteria** Published systematic reviews which were reported in Chinese or English, and meet the "PICOS", will be considered for inclusion in this review.

**Information sources** Pubmed, Embase, Cochrane Library, Chinese Biomedical Literatures Database (CBM), China National Knowledge Infrastructure (CNKI), Wang Fang Database (WF), Chinese Scientific Journal Database (VIP).

**Main outcome(s)** ① total effective rate; ② diarrhea relief time; ③ the improvement time of stool; ④ abdominal pain relief time; ⑤ the time needed to reduce fever; ⑥ treatment time; ⑦ relief time of vomiting. total effective rate; ② diarrhea relief time; ③ the improvement time of stool; ④ abdominal pain relief time; ⑤ the time needed to reduce fever; ⑥ treatment time; ⑦ relief time of vomiting.

**Data management** Endnote X9 and Excel 2018 will be used for study selection and data extraction. First, 2 independent investigators will screen titles and abstracts after removing duplicate studies in Endnote. Second, they will read the full-text of relevant studies after titles-abstracts screen, according to inclusion and exclusion criteria. Any discrepancies should be resolved by the third investigators. Finally, included studies will be coded and extracted the relevant information: study characteristics (author, publication time); participant characteristics (diagnose criteria, age, disease course, cases); intervention information (intervention detail, treatment duration, follow-up, adverse events), and treatment outcome.

**Quality assessment / Risk of bias analysis** The Cochrane Collaboration's tool to assess the risk of bias tool will be used by two reviewers for each study. The evaluation includes random sequence generation, allocation concealment, blinding of participants and assessors, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias. The assessment results will be classified into three levels: low risk, high

risk, and unclear risk. Any disagreements will be arbitrated by the third reviewer.

**Strategy of data synthesis** We will use the software RevMan 5.4 to conduct a pairwise meta-analysis of the direct comparison results obtained from the literature. Continuous data will be analyzed using mean difference (MD) or standard mean difference (SMD) with 95% confidence intervals (CI), risk ratio (RR), or odds ratio (OR) with 95% CI for dichotomous data. For the results of indirect comparison, we will use the Aggregate Data Drug Information System (ADDIS) to perform NMA on the random effects model. Comprehensive analysis of all direct and indirect results will be conducted based on the Bayesian framework and Markov Chain Monte Carlo method.

**Subgroup analysis** If the studies have high heterogeneity, subgroup analysis will be performed based on type of participants, different Tuina methods, treatment courses, different types of control group, and clinical differences to investigate the source of heterogeneity.

**Sensitivity analysis** Sensitivity analysis using the leave-one-out method will be performed to determine the effect of each individual study on the pooled results [79]. Furthermore, sensitivity analyses will be conducted by using only high-quality studies in the meta-analyses to explore the robustness of conclusion.

**Language restriction** No sensitivity analysis required in review.

**Country(ies) involved** China.

**Keywords** Tuina therapy, infantile diarrhea, systematic review, protocol.

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