INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Efficacy and safety of moxibustion in treating nocturnal enuresis in children: A protocol for systematic review and meta-analysis

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Review question / Objective: **This study aims to evaluate the efficacy and safety of moxibustion for use in treating this pediatric nocturnal enuresis.**
Condition being studied: **Nocturnal enuresis is a common multifactorial disease in childhood. In recent years, the prevalence of this disorder has exhibited an obvious upward trend. Long-term nocturnal enuresis can seriously affect a child's physical and mental growth and development, while also adversely impacting overall mental health and well-being of afflicted children and their families. Moxibustion, a traditional topical skin treatment used in traditional Chinese medicine, has been widely used in China for the treatment of childhood nocturnal enuresis, although no systematic review and meta-analysis of safety and efficacy of this treatment for pediatric nocturnal enuresis has yet been reported. Therefore, this study aims to evaluate the efficacy and safety of moxibustion for use in treating this pediatric nocturnal enuresis.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 April 2022 and was last updated on 19 April 2022 (registration number INPLASY202240119).

INTRODUCTION

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METHODS

Search strategy: PubMed, Embase, Cochrane Library, Web of Science, Medline, Cumulative Index of Nursing and Joint Health Literature (CINAHL), Chinese Biomedical (CBM), SinoMed, China National Knowledge Infrastructure (CNKI), Wanfang Data, and VIP Information (VIP) databases will be comprehensively searched. Search times will span the inception date of each database to March 31, 2022. In addition, a manual search of papers will be conducted based on inclusion of meta-analysis, dissertation, conference papers, research reports, and other gray literature related to the topics. Literature obtained from the search will be managed using Endnote20 software. Review Manager 5.3.5 software will be used to perform the systematic review and meta-analysis of selected publications. Comprehensive searches will be conducted to collect papers focusing on moxibustion and childhood nocturnal enuresis. Emphasis will be placed on collection of randomized controlled trials (RCTs) of NE in children through searches of PubMed, EMBASE, Cochrane Library, Web of Science, Medline, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Chinese biomedical literature database (SINOMED), China National Knowledge Infrastructure (CNKI) full-text database, Wanfang academic journal full text database, and Weipu Chinese technology journal full-text database (VIP). Search time for each database will be set to span the time period from database inception date to March 31, 2022. In addition, manual searches will be conducted to find other relevant research studies for use in meta-analysis, such as dissertations, conference papers, research reports, and other relevant gray literature.

Participant or population: Children of ages ranging between 5 to 18 years who experience nocturnal bedwetting that meets ICCS diagnostic criteria for NE are eligible for inclusion in the study, with no limitations based on gender, ethnicity, clinical classification, disease course, inducement, and source of cases.

Intervention: The experimental group will be subjected to moxibustion therapy (including moxa wick moxibustion, direct moxibustion, indirect moxibustion, etc.) either alone or combined with other acupuncture therapy to evaluate the effectiveness of moxibustion. The experimental group will be subjected to moxibustion therapy (including moxa wick moxibustion, direct moxibustion, indirect moxibustion, etc.) either alone or combined with other acupuncture therapy to evaluate the effectiveness of moxibustion. The control group will include pediatric NE patients treated with oral drugs (including desmopressin or desmopressin combined with anticholinergic drugs) and alarm therapy.

Comparator: The control group will include pediatric NE patients treated with oral drugs (including desmopressin or desmopressin combined with anticholinergic drugs) and alarm therapy.

Study designs to be included: Randomized controlled trials (RCTs) that were published or registered on or before March 31, 2022, with no language limitation.

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Information sources: Comprehensive searches will be conducted to collect papers focusing on moxibustion and childhood nocturnal enuresis. Emphasis will be placed on collection of randomized controlled trials (RCTs) of NE in children through searches of PubMed, EMBASE, Cochrane Library, Web of Science, Medline, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Chinese biomedical literature database (SINOMED), China National Knowledge Infrastructure (CNKI) full-text database, Wanfang academic journal full text database, and Weipu Chinese technology journal full-text database (VIP). Search time for each database will be set to span the time period from database inception date to March 31, 2022. In addition, manual searches will be conducted to find other relevant research studies for use in meta-analysis, such as dissertations, conference papers, research reports, and other relevant gray literature.

Main outcome(s): Duplicate publications or those for which we are unable to obtain full text; publications containing trial data that have been published repeatedly, publications containing incomplete data; data published in non-clinical RCTs that include animal experiments, case reports, review articles, expert experience, etc.; literature comparing different acupuncture techniques or efficacy differences between acupoint groups.

Quality assessment / Risk of bias analysis: Two designated researchers will use the Cochrane risk assessment tool to independently conduct methodological quality evaluation and offset risk assessments of included literature reports. In case of disagreement, agreement will be reached through discussion and/or consultation with a third investigator. Risks of biases will be assessed based on analysis of study characteristics related to generation of random sequence, allocation concealment, subject blind implementation, investigator blinded implementation, data completeness, selective reporting, among others. Based on final assessment results for each entry, low risk, high risk, and unclear grades will be determined then a bias risk map and summary map of bias risk will be generated using the Cochrane risk assessment tool provided with Review Manager 5.3.5 software.

Strategy of data synthesis: Statistical analysis of extracted data will be performed using Review Manager 5.3.5 software. Continuity data will be represented as a weighted mean difference value (mean difference, MD) and 95% credible interval (95% CI). Categorical variables will be expressed as relative hazard (RR) values with 95% CI values. Heterogeneity will be assessed using the Q test for qualitative analysis and heterogeneity index I for quantitative analysis (I2). For results with P>0.05 and I2<50%, a fixed effect model will be used; for results with P50%, evidence of significant heterogeneity exists that will require subgroup analysis of heterogeneity-related factors. If heterogeneity remains, a random effects model will be used to conduct pooled data analysis.

Subgroup analysis: If inter-study heterogeneity is suspected, subgroup analysis will be conducted based on age, disease duration, treatment type, treatment duration, and control treatment of included study subjects. This analysis will enable more accurate data collection and reduce the impact of interstudy heterogeneity on the final results.

Sensitivity analysis: We will perform sensitivity analysis to explore the impact of trial offset risk on the primary outcome.

Low quality trials with high offset risks will be excluded from the final data quality assessment in order to maximize the statistical significance of the final results.

Country(ies) involved: China.

Keywords: moxibustion; children's nocturnal enuresis; systematic review; meta-analysis.

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