INPLASY PROTOCOL

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None declared.

Clinical efficacy and safety of traditional Chinese medicine in the treatment of enuresis in children: a meta-analysis

Guo, ZY[1]; Yang, KJ[2]; Zeng, YJ[3]; Guo, ZD[4]; Zhang, FH[5].

Review question / Objective: **P: Children who meet the diagnostic criteria of traditional Chinese medicine or Western medicine for enuresis in children are 5-18 years old and have no gender limit. I: Treatment with traditional Chinese medicine or proprietary Chinese medicine. C: Western medicine treatment. O: (1) Primary outcome measures: total efficacy (including cure, efficacy, efficacy, improvement); (2) Secondary outcome indicators: total points of TCM certification, recurrence rate, adverse events. S: Randomized controlled trials.**

Information sources: **Computer search CNKI, Wanfang Database, Weipu Database, Pubmed, Embase and Cochrane Library. The search is limited from database to September 2022.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 September 2022 and was last updated on 28 September 2022 (registration number INPLASY202290119).

INTRODUCTION

Review question / Objective: **X P: Children who meet the diagnostic criteria of traditional Chinese medicine or Western medicine for enuresis in children are 5-18 years old and have no gender limit. I: Treatment with traditional Chinese medicine or proprietary Chinese medicine. C: Western medicine treatment. O: (1) Primary outcome measures: total efficacy (including cure, efficacy, efficacy, improvement); (2) Secondary outcome indicators: total points of TCM certification, recurrence rate, adverse events. S: Randomized controlled trials.**

Condition being studied: Enuresis in children is defined as intermittent urinary incontinence during sleep in children over 3 years of age. Enuresis in children is a common childhood disease with heterogeneous and complex causes. Central nervous system maturation, genetic factors, sleep disturbances, and delayed abnormal secretion of antidiuretic hormone can lead to the development of primary enuresis in children. Children with long-term enuresis may have problems such as impaired immune function, psychological disorders, and low self-esteem, which also have a negative impact on the quality of life of parents. At present, anticholinergic drugs, tricyclic antidepressants, artificial antidiuretics, and central stimulants are often used to treat enuresis in children, but the efficacy is poor, often leading to many side effects. For example, desmopressin has the most important side effects are water intoxication and hyponatremia, and once the drug is stopped, the recurrence rate is high. TCM treatments, such as herbs, acupuncture and tuina, are commonly used to treat enuresis in children, and many clinical studies have shown that they are effective in treating this disease and have great potential. It is not known whether the efficacy of TCM in the treatment of enuresis in children is more effective or lower than that of Western medicines, so this meta-analysis included randomized controlled trials to investigate the difference between the effects of TCM and Western medicine in the treatment of enuresis in children, with the aim of providing a basis for clinical decision-making.

METHODS

Search strategy: Computer search CNKI, Wanfang Database, Weipu Database, Pubmed, Embase and Cochrane Library. The search is limited from database to September 2022. Adopt a search method that combines the subject word with the free word. Taking PubMed as an example, its search query is: ((("enuresis"[Mesh]) OR (((((((Diurnal Enuresis[Title/Abstract]) OR (Enuresis, Diurnal[Title/Abstract])) OR (Daytime Wetting[Title/Abstract])) OR (Wetting, Daytime[Title/Abstract])) OR (Daytime Urinary Incontinence[Title/Abstract])) OR (Incontinence, Daytime Urinary[Title/Abstract])) OR (Urinary Incontinence, Daytime[Title/Abstract]))) AND (("Medicine, Chinese Traditional"[Mesh]) OR (((((((Traditional Chinese Medicine[Title/Abstract]) OR (Chinese Medicine[Title/Abstract])) OR (Chinese Herbal Medicine[Title/Abstract])) OR (Herbal Medicine[Title/Abstract])) OR (Medicine, Herbal[Title/Abstract])) OR (Zhongyi[Title/Abstract])) OR (Zhongyao[Title/Abstract]))))) AND ((clinical[tiab] AND trial[tiab]) OR "clinical trials as topic"[mesh] OR "clinical trial"[pt] OR random*[tiab] OR "random allocation"[mesh] OR "therapeutic use"[sh]).

Participant or population: Children who meet the diagnostic criteria of traditional Chinese medicine or Western medicine for enuresis in children are 5-18 years old and have no gender limit.

Intervention: Treatment with traditional Chinese medicine or proprietary Chinese medicine.

Comparator: Western medicine treatment.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: 1.1 Inclusion criteria1.1.1 Type of study: randomized controlled trials, with or without blinding. Languages are limited to Chinese and English.1.1.2 Research subjects: children who meet the diagnostic criteria of traditional Chinese medicine or Western medicine for childhood enuresis (citation in the literature), aged 5-18 years old, gender is not limited.1.1.3 Interventions: Experimental group: oral Chinese medicine or proprietary Chinese medicine treatment, control group: Western medicine treatment, both groups can combine other therapies, except for traditional Chinese medicine external treatment and acupuncture and massage and other traditional Chinese medicine characteristic therapies, the

course of treatment is consistent.1.1.4 Outcome indicators: (1) Primary outcome measures: total effective (including cure, efficacy, efficacy, improvement); (2) Secondary outcome indicators: total points of TCM certification, recurrence rate, adverse events.1.1.5 Exclusion criteria: (1) studies in which the research object does not match; (2) Research on inconsistencies in interventions; (3) Studies in which the same study is published repeatedly, the data are incomplete, and the full text cannot be obtained; (4) Overview, case report, theoretical discussion, experience summary, etc.Compliance with any of the above can be excluded.

Information sources: Computer search CNKI, Wanfang Database, Weipu Database, Pubmed, Embase and Cochrane Library. The search is limited from database to September 2022.

Main outcome(s): Total efficacy.

Additional outcome(s): Total points of TCM certification, recurrence rate, adverse events.

Quality assessment / Risk of bias analysis: The quality of the included literature was evaluated using the risk assessment tool for RCTs recommended by the Cochrane manual: (1) random sequence generation; (2) Assign hidden; (3) The implementation of blinding (including blinding subjects and interventionists, blinding results evaluators); (4) Completeness of result data; (5) Selective reporting; (6) Other sources of bias. The results are independently evaluated by 2 researchers, and the results are cross-checked, and in case of disagreement, they are discussed and resolved or referred to a third investigator for assistance.

Strategy of data synthesis: Adopt Rev Man 5. 4The software performs statistical analysis of the extracted data. The relative risk (RR) is used as the effect analysis statistic for the dichotomous variables; The continuity variable uses the standardized mean difference (SMD) as the effect analysis statistic, and sets a 95% confidence interval (CI), and the $P<0.05$ indicates that the difference is statistically significant. Heterogeneity is assessed using I2 tests and standard chi-square tests, and analytical effects models are selected based on the size of the heterogeneity. If the $I2 < 50\%$ and the $P> 0.1$, the heterogeneity between the studies is considered to be small, and the fixed-effect model is used for meta-analysis. If $I2 \geq 50\%$ or $P \leq 0.1$, a random-effects model is used for meta-analysis, and subgroup analysis and sensitivity analysis are performed to explore the source of heterogeneity.

Subgroup analysis: Subgroup analyses were performed according to the treatment measures used in the control group.

Sensitivity analysis: Data from the remaining papers were combined after deleting any one of them in turn, and if the difference between the results before and after deletion was not significant, the sensitivity analysis was considered to have been passed.

Country(ies) involved: China.

Keywords: Enuresis in children; Traditional Chinese medicine treatment; Western medicine treatment; Efficient; Randomized controlled trials.

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