INPLASY PROTOCOL

To cite: Qi et al. Huanglian Ejiao Decoction for insomnia: Systematic review and meta-analysis. Inplasy protocol 202240043. doi: 10.37766/inplasy2022.4.0043

Received: 07 April 2022

Published: 07 April 2022

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Support: **Hebei administration of TCM.**

Review Stage at time of this submission: **Data analysis.**

Conflicts of interest:
None declared.

Huanglian Ejiao Decoction for insomnia: Systematic review and meta-analysis

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Review question / Objective: **P: All included research subjects meet the commonly used diagnostic criteria for insomnia in Western medicine and traditional Chinese medicine, such as the International Classification of Sleep Disorders criteria, the Chinese Guidelines for the Diagnosis and Treatment of Insomnia, and the Guiding Principles for Clinical Research on New Drugs of Traditional Chinese Medicine. I: The experimental group is treated with Huanglian Ejiao Decoction, Huanglian Ejiao Decoction combined with Western medicine, Huanglian Ejiao Decoction modified or Huanglian Ejiao Decoction modified combined with Western medicine. C: Commonly used Western medicine are used for treatment, specifically benzodiazepines such as estazolam, diazepam, alprazolam, or non-benzodiazepines such as zopiclone. O: The primary outcome measure are Pittsburgh Sleep Quality Index (PSQI) and clinical response rate. The secondary outcome measure is clinical adverse reaction rate. S: Randomised controlled trials are used to conduct research.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 April 2022 and was last updated on 07 April 2022 (registration number INPLASY202240043).

INTRODUCTION

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Western medicine. C: Commonly used Western medicine are used for treatment, specifically benzodiazepines such as estazolam, diazepam, alprazolam, or non-benzodiazepines such as zopiclone. O: The primary outcome measure are Pittsburgh Sleep Quality Index (PSQI) and clinical response rate. The secondary outcome measure is clinical adverse reaction rate. S: Randomised controlled trials are used to conduct research.

Condition being studied: Insomnia is the inability to fall asleep naturally or to maintain deep sleep for long periods of time. Caused by functional impairment, poor mental state or decreased quality of life, insomnia is accompanied by adverse symptoms such as pain, anxiety, depression, and daytime dysfunction. Patients with insomnia have potential risks of hypertension, diabetes and other diseases.

METHODS

Participant or population: Insomnia.

Intervention: The experimental group is treated with Huanglian Ejiao Decoction, Huanglian Ejiao Decoction combined with Western medicine, Huanglian Ejiao Decoction modified or Huanglian Ejiao Decoction modified combined with Western medicine.

Comparator: Commonly used Western medicine are used for treatment, specifically benzodiazepines such as estazolam, diazepam, alprazolam, or non-benzodiazepines such as zopiclone.

Study designs to be included: Randomised controlled trials.

Eligibility criteria: Only clinical RCTs are included. Studies meeting one of the following criteria should be excluded: (1) non-randomized controlled trials. (2) non-clinical studies such as reviews, animal/cell studies, case reports. (3) studies with missing or incorrect data. (4) studies with duplicate publications.

Information sources: PubMed, Embase, Web of Science, the Cochrane Library, China Biology Medicine disc (CBM), China National Knowledge Infrastructure (CNKI), Chinese Science and Technology Periodical Database (VIP) and Wanfang Database.

Main outcome(s): The main outcome measure are Pittsburgh Sleep Quality Index (PSQI) and clinical efficacy.

Quality assessment / Risk of bias analysis: Use the risk of bias assessment tool for RCTs in the Cochrane Handbook of Systematic Reviews.

Strategy of data synthesis: Statistical analysis of data is performed by Review Manager 5.3 software and Stata 16.0. Effect measures for dichotomous variables are expressed as relative risk (RR), and effect measures for continuous variables are expressed as weighted mean square error (WMD), with estimates and 95% confidence intervals (95% CI) for both effect sizes. The heterogeneity among the included study results is analyzed by χ^2 test (the test level was a=0.05). If I^2=50%, the heterogeneity is small, and a fixed effect model was used for meta-analysis. If $I^2$50%, the heterogeneity is small. The heterogeneity is large, and further sensitivity analysis and subgroup analysis are used to explore the source of heterogeneity. The distribution symmetry of the funnel plot and the P value calculated by Egger's test are used to judge whether the corresponding study has publication bias.

Subgroup analysis: For PSQI, the subgroup meta-analysis is performed based on the intervention assignment covariate. One group is treated with Huanglian Ejiao Decoction only, and the other group is treated with Huanglian Ejiao Decoction combined with Western medicine.

Sensitivity analysis: For PSQI, the sensitivity analysis is performed.

Country(ies) involved: China.

Keywords: Traditional Chinese medicine, insomnia, systematic review, meta-analysis, Huanlianejiao Decoction.

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