INPLASY PROTOCOL

To cite: Qi et al. Liu Wei Di Huang Wan for insomnia: A systematic review and meta-analysis. Inplasy protocol 202250169. doi: 10.37766/inplasy2022.5.0169

Received: 31 May 2022

Published: 31 May 2022

Corresponding author:
Yinghui Qi

1262085251@qq.com

Author Affiliation:
Hebei North University.

Support: **Hebei administration of TCM.**

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

Conflicts of interest:
None declared.

Liu Wei Di Huang Wan for insomnia: A systematic review and meta-analysis

Qi, YH[1]; Zhang, CH[2]; Xue, XJ[3].

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 Classification of Mental Disorders Third Edition, the Chinese Guidelines for the Diagnosis and Treatment of Insomnia and the Chinese Guidelines for the Diagnosis and Treatment of Adult Insomnia. I: The experimental group is treated with Liu Wei Di Huang Wan, Liu Wei Di Huang Decoction or Liu Wei Di Huang Wan combined with Western medicine. C: Commonly used Western medicine are used for treatment, specifically benzodiazepines such as Estazolam, Diazepam and Alprazolam. 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 31 May 2022 and was last updated on 31 May 2022 (registration number INPLASY202250169).

INTRODUCTION

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 Classification of Mental Disorders Third Edition, the Chinese Guidelines for the Diagnosis and Treatment of Insomnia and the Chinese Guidelines for the Diagnosis and Treatment of Adult Insomnia. I: The**

experimental group is treated with Liu Wei Di Huang Wan, Liu Wei Di Huang Decoction or Liu Wei Di Huang Wan combined with Western medicine. C: Commonly used Western medicine are used for treatment, specifically benzodiazepines such as Estazolam, Diazepam and Alprazolam. 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 a sleep disorder that makes people fall asleep or maintain deep sleep for a long period difficultly. Insomnia is accompanied by mental fatigue. It can also induce palpitations, chest paralysis, vertigo, headache, stroke disease and many other diseases.

METHODS

Participant or population: Insomnia.

Intervention: The experimental group is treated with Liu Wei Di Huang Wan, Liu Wei Di Huang Decoction or Liu Wei Di Huang Wan combined with Western medicine.

Comparator: Commonly used Western medicine are used for treatment, specifically benzodiazepines such as Estazolam, Diazepam and Alprazolam.

Study designs to be included: Randomised controlled trials.

Eligibility criteria: For this systematic review, only clinical RCTs were included. Studies that met one or more of the following criteria were excluded: (1) Not RCTs. (2) Non-clinical research, such as reviews, animal/cell experiments, and case reports. (3) Studies with missing or erroneous data. (4) Republished studies published. (5) Studies with incompatible intervention.

Information sources: Pubmed, EMbase, Web of Science, 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 Pittsburgh Sleep Quality Index (PSQI) and efficacy were the key outcome measures.

Quality assessment / Risk of bias analysis: Use the Cochrane Handbook for Systematic Reviews of interventions to evaluate the risk of bias in each of the included RCTs.

Strategy of data synthesis: The data was statistically analyzed using Review Manager 5.3 and Stata 16.0. The effect measure for the binary variables was relative risk (RR). The effect measure for continuous variables was weighted mean squared deviation (WMD). Both effect measures were provided estimates with 95 percent confidence intervals (95%CI). The chi-square test (test level a=0.05) was used to assess heterogeneity between the outcomes of the included RCTs. The heterogeneity of included RCTs was minor if I2 $<$50%, hence fixed effects models were utilized for this meta-analysis. If I2>50%, there was a high heterogeneity among the included RCTs. The source of their heterogeneity was further investigated using sensitivity analysis and subgroup analysis. The funnel plot's distribution symmetry and the Egger's test were used to analyze the reporting bias of the included RCTs.

Subgroup analysis: For PSQI, the subgroup meta-analysis is performed based on the type of disease of the patients. One group is multiple diseases group due to the inclusion of patients with other underlying diseases in addition to insomnia. The other group is a single disease group due to the inclusion of patients with insomnia only.

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

Country(ies) involved: China.

Keywords: Traditional Chinese medicine, insomnia, systematic review, meta-analysis, Liu Wei Di Huang Wan.

Contributions of each author:
Author 1 - Yinghui Qi.
Author 2 - Chunhui Zhang.
Author 3 - Xiujuan Xue.