INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Efficacy and safety of Jieyu Anshen Granule for insomnia
A protocol for systematic review and meta-analysis

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Review question / Objective: **Explore Jieyu Anshen granule of Chinese patients with insomnia insomnia to evaluate the safety and efficacy of treatment.**
Condition being studied: **At present, insomnia has seriously threatened people's physical and mental health, and brought heavy burden to individuals, families and society. In China, the Jieyu Anshen granule are widely used in the treatment of insomnia, but there is still a lack of evidence-based medical evaluation.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 February 2022 and was last updated on 22 February 2022 (registration number INPLASY202220094).

INTRODUCTION

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METHODS

Participant or population: **Regardless of age or gender, the patients were in**

accordance with the 2017 version of the Chinese guide to diagnosis and treatment of insomnia insomnia diagnostic criteria in, its standard as follows:Patients with difficulty falling asleep, or difficult to maintain sleep, or wake up early, or difficult to fall asleep without intervention; and nighttime sleep difficulties related to one or more performance, such as fatigue, attention, memory drops, daytime sleepiness, initiative, the quality of insomnia; the above performance can't be other sleep disorders better explanation.

Intervention: Jieyu Anshen granule.

Comparator: Oral hypnotic drugs, Benzodiazepine receptor agonists (BzRAs, such as Alprazolam, estazolam, zopiclone) or Melanoid receptor agonists (such as ramelteon).

Study designs to be included: According to the retrieval strategies, randomized controlled trials (RCTs) on the Jieyu Anshen granule for insomnia were obtained from CNKI, WanFang, VIP, PubMed, Embase and Cochrane Library, regardless of publication date, or language. Studies were screened based on inclusion and exclusion criteria, and the Cochrane risk bias assessment tool was used to evaluate the quality of the studies. The meta-analysis was performed using RevMan 5.3 and STATA 14.2 software. Ultimately, the evidentiary grade for the results will be evaluated.

Eligibility criteria: The PICOS principles were given full consideration to establish the inclusion and exclusion criteria of this systematic review.

Information sources: Studies were obtained from the China National Knowledge Infrastructure (CNKI), Wan Fang Data, Chinese Scientifific Journals Database (VIP), PubMed, Embase and Cochrane Library, regardless of publication date or language. CNKI, WanFang, VIP, PubMed, Embase and Cochrane Library.

Main outcome(s): This study will evaluate the effifficacy and safety of the Jieyu Anshen granule in the treatment of insomnia and provide a more reasonable choice of medication in clinical practice.

Quality assessment / Risk of bias analysis: Two researchers (Bingchen Li and Zerun Zhang) assessed the quality of the included RCTs independently by utilizing the Cochrane risk of bias assessment tool. As specifified by Cochrane Handbook V.5.1.0, the following sources of bias were considered: random sequence generation, allocation concealment, participant blinding, outcome assessor blinding, incomplete outcome data, selective reporting, and other sources of bias. Each domain was rated as having a high, low or unclear risk of bias as Appropriate[16]. The 2 reviewers resolved any disagreements through discussion, and a third reviewer (Lu Zhang) was involved if a consensus could not be reached.

Strategy of data synthesis: The meta-analysis was performed with Review Manager 5.3 and STATA 14.2 software. The outcomes were mainly represented by the mean difference (MD) or odds ratio (OR) with 95% confidence intervals, and a P value <.05 was considered significant. The Cochrane Q-test and I2 statistics were used to assess heterogeneity. When P50% indicated statistical heterogeneity, a random effects model was used to calculate the outcomes; otherwise, the fixed effect model was considered.

Subgroup analysis: If there was high heterogeneity in the studies, we performed subgroup analyses to explore the differences in age, sex, interventions, and course of disease/treatment.

Sensitivity analysis: To ensure robustness of the combined results, sensitivity analyses were performed to assess the impact of studies with a high risk of bias. We compared the results to determine whether lower quality studies should be excluded.

Country(ies) involved: China.

Keywords: insomnia, Jieyu Anshen granule, protocol, systematic review, meta-analysis.

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