INPLASY PROTOCOL

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None.

Effectiveness comparisons of Chinese patent medicine on insomnia: A protocol for systematic review and Bayesian network meta-analysis

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Review question / Objective: **o compare the efficacy of different CPM on insomnia, and rank the intervention measures according to the efficacy, in order to provide evidence-based medical evidence for clinical treatment plans.**
Condition being studied: **In recent years, the incidence of insomnia is increasing. However, the existing therapy methods for cannot fundamentally treat the disease. Meanwhile, Chinese patent medicine (CPM) plays an active role in the treatment of insomnia. However, there is no comparison and ranking of the efficacy of every CPM. Therefore, our study will use network meta-analysis (NMA) to compare the efficacy of different CPM on insomnia, in order to provide evidence-based medical evidence for clinical treatment.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 December 2020 and was last updated on 24 December 2020 (registration number INPLASY2020120121).

INTRODUCTION

Review question / Objective: **To compare the efficacy of different CPM on insomnia, and rank the intervention measures according to the efficacy, in order to provide evidence-based medical evidence for clinical treatment plans.**

Condition being studied: **In recent years, the incidence of insomnia is increasing. However, the existing therapy methods for cannot fundamentally treat the disease. Meanwhile, Chinese patent medicine (CPM) plays an active role in the treatment of insomnia. However, there is no comparison and ranking of the efficacy of every CPM. Therefore, our study will use network meta-**

analysis (NMA) to compare the efficacy of different CPM on insomnia, in order to provide evidence-based medical evidence for clinical treatment.

METHODS

Search strategy: We will search CNKI, Wanfang, VIP, CBM, Pubmed, Cochrane Library, EMbase for the randomized controlled trials (RCTs) of CPM in the treatment of insomnia, and then screen the relevant documents published at home and abroad. The limited publication time is from the establishment of the database to December 31, 2020. According to different database conditions, the subject words, key words and free words will be comprehensively searched to ensure the systematicness and integrity of the search.

Participant or population: According to the diagnostic criteria for insomnia promulgated by European Sleep Research Society (ESRS), we will include patients over 18 years of age who have a clear diagnosis of insomnia. There will be no restrictions on sample size, treatment time, types of therapeutic drugs, race, culture, region and gender.

Intervention: The treatment group will be treated with a single CPM or a single CPM plus conventional western medicine or placebo, which must be the same as the control group. There will be no restriction on dosage form, dosage and usage of CPM.

Comparator: The control group will be treated with conventional western medicine or placebo.

Study designs to be included: We will include randomized controlled trials (RCTs) with complete case data, whether blind or not, regardless of country or region, and the language will be limited to Chinese and English.

Eligibility criteria: Patients diagnosed with insomnia.

Information sources: We will search CNKI, Wanfang, VIP, CBM, Pubmed, Cochrane Library, EMbase for the randomized controlled trials (RCTs) of CPM in the treatment of insomnia, and then screen the relevant documents published at home and abroad.

Main outcome(s): The primary outcome indicator will be clinical efficacy.

Additional outcome(s): The secondary outcome indicators will include Pittsburgh Sleep Quality Index (PSQI) points, TDL Quality of Life Assessment Scale (TDL-QOLAS) points, and adverse events.

Data management: Two researchers will independently screen the literature, preliminarily screen the retrieval results by reading the topics and abstracts, and combining the inclusion and exclusion criteria, and then cross-check. In case of differences, two researchers will consult a third party to discuss and solve. The extracted data will include the first author, published year, sample size, basic information of patients, baseline situation, randomized method, intervention measures, treatment course, outcome index, etc.

Quality assessment / Risk of bias analysis: The quality evaluation of each RCT will be independently evaluated by two researchers according to the improved Jadad scale. In case of disagreement, they will reach an agreement through negotiation or consult a third party to solve the problem. The evaluation contents will include: the generation of random sequence, the scheme of allocation and concealment, the implementation of blind method, withdrawal and missing visit. The total score of 1 ~ 2 is low quality, 3 ~ 4 is medium quality and 5 ~ 7 is high quality. In the evaluation process, if there is a lack of data, try to get it by contacting the author, and if it is impossible to get it, screen out the literature as appropriate.

Strategy of data synthesis: We will use Revman 5.3, Stata 15.1 and ADDIS 1.16.8 software for NMA. The Binary variables will

be expressed by odds ratio (OR) and its 95% confidence interval (CI) while the continuous variables will be expressed by mean difference (MD) or standardized mean difference (SMD) and its 95% confidence interval (CI). ?2 test will be used to analyze the heterogeneity and I2 to evaluate the heterogeneity. If I2 ≤ 50%, the heterogeneity is small, and the fixed effect model will used to combine the effect amount; if I2 > 50%, the heterogeneity is large, after excluding the influence of significant clinical heterogeneity, if the heterogeneity is small, the fixed effect model will be used; otherwise, subgroup analysis or sensitivity analysis will be used to deal with obvious clinical heterogeneity, eliminate heterogeneity factors or use random effects model to merge analysis. When there is a closed loop, the consistency of direct comparison and indirect comparison passes the consistency test. When the consistency test inconsistency factor (IF) is close to 0 or the hypothesis test OR is close to 1, the direct and indirect evidences are considered to be consistent. The funnel diagram will be drawn to identify whether there is small sample effect evaluation. 4 Markov chain-Monte Carlo (MCMC) will be used to set the initial value. The number of initial update iterations of the model will be set to 50,000, and the number of continued update iterations will be set to 20,000. The first 50,000 will be used for annealing to eliminate the influence of the initial value. Sampling will start after 50,001. When the potential scale reduction factor (PSRF) tends to 1, the degree of convergence is satisfactory. We will draw the surface under cumulative ranking area (SUCRA) to predict the order of efficacy. The difference will be statistically.

Subgroup analysis: If the heterogeneity is small, the fixed effect model will be used; otherwise, subgroup analysis or sensibility analysis will be used to deal with obvious clinical heterogeneity, eliminate heterogeneity factors or use random effects model to merge analysis.

Sensibility analysis: If the heterogeneity is small, the fixed effect model will be used; otherwise, subgroup analysis or sensibility analysis will be used to deal with obvious clinical heterogeneity, eliminate heterogeneity factors or use random effects model to merge analysis.

Country(ies) involved: China.

Keywords: insomnia; Chinese patent medicine; network meta-analysis; protocol.

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