

# INPLASY PROTOCOL

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**Review Stage at time of this submission:** Piloting of the study selection process.

**Conflicts of interest:**  
None declared.

## Efficacy of Integrated Traditional Chinese Medicine and Western Medicine in the treatment of post-stroke insomnia: A protocol for systematic review and meta-analysis of randomized controlled trials

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**Review question / Objective:** Western medicine (WM) has played an important role in the treatment of post-stroke insomnia (PSI) in China, and the traditional Chinese medicine (TCM) therapy based on Chinese characteristics is also effective. Combined with China's national conditions, we therefore conducted this meta-analysis to compare the clinical efficacy of integrated traditional Chinese and Western medicine (INTEGRATED TCM WM) therapy and WM alone for PSI.

**Eligibility criteria:** (1)The type of study is all randomized controlled trials (RCTs) of INTEGRATED TCM WM or WM alone in the treatment of PSI. (2)The study objects are PSI patients with clear and standardized diagnostic criteria, regardless of case source, age, gender and race. (3)The control group only received conventional WM treatment, and the experimental group was treated with TCM on the basis of the control group. (4)According to the efficacy evaluation index, including clinical effective rate or Pittsburgh sleep quality index (PSQI) score.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 April 2021 and was last updated on 04 September 2021 (registration number INPLASY202140028).

### INTRODUCTION

**Review question / Objective:** Western medicine (WM) has played an important role in the treatment of post-stroke insomnia (PSI) in China, and the traditional Chinese medicine (TCM) therapy based on Chinese characteristics is also effective. Combined with China's national conditions,

we therefore conducted this meta-analysis to compare the clinical efficacy of integrated traditional Chinese and Western medicine (INTEGRATED TCM WM) therapy and WM alone for PSI.

**Condition being studied:** Post-stroke insomnia (PSI) is a common type of stroke-related sleep disorders (SSD). PSI is a

disease that first appears after stroke and reaches the diagnostic criteria of insomnia. It is an important public health problem associated with high prevalence rate, accounting for about 38.2%, which increases the risk of death and recurrence of stroke, and seriously affects the recovery and prognosis of patients, but it does not draw enough attention by both patients and doctors. Sleep occupies 1/4-1/3 of life time in most humans and is an essential physiological process to maintain human health. Good sleep is the basis of a high quality of life and the completion of a variety of social activities. Frequent insomnia is easy to cause depression, anxiety and other psychiatric diseases. In addition, insomnia can impair the neurological function and cognitive function, reduce the quality of life, and cause the recurrence of stroke. Western medicine (WM) has played an important role in the treatment of post-stroke insomnia (PSI) in China, and the traditional Chinese medicine (TCM) therapy based on Chinese characteristics is also effective. Combined with China's national conditions, we therefore conducted this meta-analysis to compare the clinical efficacy of integrated traditional Chinese and Western medicine (INTEGRATED TCM WM) therapy and WM alone for PSI.

## METHODS

**Participant or population:** The study objects are PSI patients with clear and standardized diagnostic criteria.

**Intervention:** Integrated traditional Chinese and Western Medicine.

**Comparator:** Patients received conventional western medicine treatment alone.

**Study designs to be included:** Only clinical randomized controlled trials (RCTs) were eligible.

**Eligibility criteria:** 1)The type of study is all randomized controlled trials (RCTs) of INTEGRATED TCM WM or WM alone in the treatment of PSI. (2)The study objects are

PSI patients with clear and standardized diagnostic criteria, regardless of case source, age, gender and race. (3)The control group only received conventional WM treatment, and the experimental group was treated with TCM on the basis of the control group.(4)According to the efficacy evaluation index, including clinical effective rate or Pittsburgh sleep quality index (PSQI) score.

**Information sources:** PubMed, Wangfang Database, CBM(Chinese Biology Medical Database), VIP Database and CNKI(Chinese National Knowledge Infrastructure).

**Main outcome(s):** The main outcomes of this review will focus on the efficacy rate and the PSQI Total score.

**Data management:** We will perform data collection and analysis according to Cochrane Review procedures. Two review authors independently extracted data and evaluated the quality of the included literatures. In case of disagreement, they were discussed or decided by an independent third review author.

**Quality assessment / Risk of bias analysis:** Two researchers independently assessed the methodological quality of each paper by using the Cochrane risk of bias tools. The main items include random sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting and other bias. Each item is divided into "low risk", "unclear risk" and "high risk".

**Strategy of data synthesis:** Revman5.3 software was used for meta-analysis. Relative risk (RR) with 95% confidence interval (CI) was calculated for dichotomous data, and mean difference (MD) with 95% CI was calculated for continuous data.  $P < 0.05$  was a statistically significant difference for all analyses. The level of statistically significant heterogeneity was set at  $P < 0.1$ . In addition,  $I^2$  value was used to analyze the heterogeneity quantitatively. If  $P > 0.1$  and  $I^2 \leq 50\%$ , meta analysis adopted fixed-effect; If  $P > 0.1$  and  $I^2 > 50\%$ , meta analysis adopted random-

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effect. If the random-effect was used, we would perform a sensitivity analysis or subgroup analysis to clarify the source of heterogeneity. Funnel plot was used to analyze publication bias.

**Subgroup analysis:** We would perform a sensitivity analysis or subgroup analysis to clarify the source of heterogeneity when there is significant clinical heterogeneity in the included studies(such as sleep quality, sleep onset latency, sleep duration, sleep efficiency, daytime dysfunction, sleep disturbance and sleep medication).

**Sensitivity analysis:** To assess the influence of each individual study, leave-one-out sensitivity analysis was performed iteratively by removing one study at a time to confirm that the findings were not influenced by any single study.

**Language:** Both Chinese and English can be included in the study.

**Country(ies) involved:** China.

**Keywords:** Post-stroke insomnia; Integrated traditional Chinese and Western medicine; Western medicine; Efficacy.

**Contributions of each author:**

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