

# INPLASY PROTOCOL

## Pestle needle for insomnia: a systematic review and meta-analysis

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**Support:** The department of  
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**Review Stage at time of this  
submission:** The review has  
not yet started.

**Conflicts of interest:**  
None.

**Review question / Objective:** Is pestle needle effective and  
safe for insomnia patients?

**Condition being studied:** Insomnia patients.

**Information sources:** The following electronic databases will  
be searched by two independent reviewers: PubMed,  
Cochrane Library, EMBASE, Springer, China National  
Knowledge Infrastructure (CNKI), Wanfang, and Chinese  
Biomedical Literature Database (CBM).

**INPLASY registration number:** This protocol was registered with  
the International Platform of Registered Systematic Review and  
Meta-Analysis Protocols (INPLASY) on 22 October 2020 and was  
last updated on 22 October 2020 (registration number  
INPLASY2020100083).

### INTRODUCTION

**Review question / Objective:** Is pestle  
needle effective and safe for insomnia  
patients?

**Condition being studied:** Insomnia patients

### METHODS

**Search strategy:** The following electronic  
databases will be searched by two

independent reviewers: PubMed, Cochrane  
Library, EMBASE, Springer, China National  
Knowledge Infrastructure (CNKI), Wanfang,  
and Chinese Biomedical Literature  
Database (CBM). All randomized controlled  
trials on pestle needle for insomnia in  
electronic databases from inception to  
October 1st, 2020 with language restricted  
in Chinese and English will be included in  
the study, while unpublished studies will  
not be sought. Searches will be re-run prior  
to the final analysis.

**Participant or population:** Inclusion: adults with insomnia (as diagnosed using any recognised diagnostic criteria). Exclusion: acute medical conditions or pregnancy.

**Intervention:** Types of acupuncture including pestle needle and combination therapy with pestle needle will be included.

**Comparator:** Control group. A group contains traditional therapies, drug, no treatment, placebo, diet and exercise therapy.

**Study designs to be included:** We will include randomized clinical trial (RCT) with no limitation of blinding. The animal mechanism studies, case reports, self-pre and post-control, or non-RCTs will be excluded.

**Eligibility criteria:** Types of acupuncture including pestle needle and combination therapy with pestle needle will be included.

**Information sources:** The following electronic databases will be searched by two independent reviewers: PubMed, Cochrane Library, EMBASE, Springer, China National Knowledge Infrastructure (CNKI), Wanfang, and Chinese Biomedical Literature Database (CBM).

**Main outcome(s):** Pittsburgh Sleep Quality Index (PSQI) and Self-improvement scale of sleep to assess the sleepy quality of insomnia patients.

**Additional outcome(s):** Self-rating anxiety scale (SAS) and self-rating depression scale (SDS) to assess the anxiety and depression state of insomnia patients. Side effects assesses the safety of interventions, including pneumothorax, bleeding, serious discomfort, subcutaneous nodules, and infection in this review.

**Quality assessment / Risk of bias analysis:** The risk of bias in each study will be assessed using the Cochrane Collaboration Risk of Bias Tool including generation of the allocation sequence, allocation concealment, blinding of investigators and

participants, blinding of outcome assessors, incomplete outcome data, and the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) checklist.

**Strategy of data synthesis:** We may conduct narrative synthesis if meta-analysis is not appropriate (e.g., incidence of adverse events of acupuncture). RevMan V.5.3 will be employed for data analysis when meta-analysis is possible. The MD with 95% CIs will be used to assess continuous outcomes, while the RR with 95% CIs will be used for dichotomous data. If  $I^2 \geq 30\%$ , a random-effects model will be used to synthesize the data. Sensitive analysis will be conducted to test the stability of this synthesis.

**Subgroup analysis:** A subgroup analysis will be performed according to control intervention and different outcomes to explore the causes of heterogeneity including clinical or methodological reasons.

**Sensibility analysis:** We will explore the impact of study quality by dividing studies into two groups based on the Jadad score<sup>19</sup>: high-quality study (Jadad score  $\geq 4$ ) and low-quality study (Jadad score  $\leq 3$ ). In addition, the publication bias was inspected by funnel plots.<sup>20</sup> We set a priori  $\alpha$  level of 0.05 for between-group differences.

**Language:** Language restricted in Chinese and English.

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

**Keywords:** pestle needle; insomnia; systematic review.

**Contributions of each author:**

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