

# INPLASY PROTOCOL

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

**Conflicts of interest:** No.

## Chinese Herbs Medicine Huatan Huoxue Prescription for Obstructive Sleep Apnea Hypopnea Syndrome as Complementary Therapy : a protocol for a systematic review and meta-analysis

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**Review question / Objective:** To evaluate whether Huatan Huoxue prescription is effective in treating Sleep Apnea Syndrome.

**Condition being studied:** Obstructive sleep apnea hypopnea syndrome (OSAHS) is a common and potentially dangerous sleep disorder accompanied by cardio-cerebrovascular events and multiple organ injury, which is caused by airway occlusion during sleep secondary to pharyngeal collapse and is characterized by repetitive breathing interruptions when Sleeping

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 May 2020 and was last updated on 21 May 2020 (registration number INPLASY202050079).

### INTRODUCTION

**Review question / Objective:** To evaluate whether Huatan Huoxue prescription is effective in treating Sleep Apnea Syndrome.

**Rationale:** To explore the efficacy and safety of HTHXP through data analysis.

**Condition being studied:** Obstructive sleep apnea hypopnea syndrome (OSAHS) is a common and potentially dangerous sleep disorder accompanied by cardio-cerebrovascular events and multiple organ injury, which is caused by airway occlusion during sleep secondary to pharyngeal collapse and is characterized by repetitive breathing interruptions when Sleeping.

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## METHODS

**Search strategy:** We were searched the following Electronic databases from their inceptions: PubMed, the Cochrane Library, Embase, the China National Knowledge Infrastructure (CNKI), Wanfang Database, Chinese Science and Technology Periodical Database (VIP), and Chinese Biomedical Literature Database (CBM). Search terms consist of disease (Sleep Apnea Syndrome, sleep disorderse) and intervention (Huatan Huoxue prescription, Huatan, Huoxue). We'll also check the reference lists of eligible articles obtained from additional studies. #1 Huatan Huoxue prescription OR Huatan OR Huoxue #2 Sleep Apnea Syndrome OR sleep disorderse #1AND#2.

**Participant or population:** Patients with Sleep Apnea Syndrome.

**Intervention:** Huatan Huoxue prescription (no injection; no pill).

**Comparator:** Traditional western medicine treatment.

**Study designs to be included:** Clinical randomized controlled trial.

**Eligibility criteria:** (1)Studies: clinical randomized controlled trials. (2)Participants: patients diagnosed with OSAHS according to "2010 Guidelines for the Diagnosis and Treatment of Pulmonary Hypertension in China" [14]. (3)Interventions:the treatment group was treated with HTHXM or combined with CWM, the control group was treated with CWM alone.There was no limitation patient's gender, race, age, and the course and severity of the disease.

**Information sources:** Six databases including EMbase, Cochrane, PubMed, China National Knowledge Infrastructure (CNKI),Wan Fang, and VIP Data were searched from their inception to March 1, 2020. If any, we would try to contact the original study authors for the information we need. We would perform a manual search to track the references of relevant literature.

**Main outcome(s):** Effective rate.

**Additional outcome(s):** AMI, SaO<sub>2</sub>, ESS, adverse reactions.

**Data management:** We performed and completed meta analysis and methodological evaluation by Review Manager 5.3.3 and statas 12.0 software.Study selection, data extraction, quality assessment, and assessment of risk bias will be performed by 2 reviewers independently. Odds ratios and correlative 95% confidence intervals will be calculated to present the association between the HTHXP and western medicine treatment using Review Manager version 5.3 when there is sufficient available data.

**Quality assessment / Risk of bias analysis:** In accordance with recommendations in the Cochrane Handbook of Systematic Reviews of Interventions, two reviewers independently evaluated the methodological quality of included trials using the Cochrane risk of bias assessment tool that included the following items: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias. For each item, ROB was graded as high, low, or unclear. If the evaluation results were inconsistent, issues were resolved by rechecking the source papers and further discussions with the third reviewer.

**Strategy of data synthesis:** The meta-analysis was performed using Reviewer Manager Software, version 5.3. We defined  $P \leq 0.05$  as statistically significant between studies. Dichotomous outcomes will be presented as risk ratios (RRs) and 95% confidence intervals (95% CI), whilst continuous outcomes will be presented as weight mean differences (WMDs) and 95% CI. The studies' heterogeneity was evaluated by  $\chi^2$  test and Higgins  $I^2$  test, when  $I^2 \leq 50\%$ ,  $P \geq 0.10$ , the fixed effect model was used; otherwise, a random effects model will be used after excluding significant clinical heterogeneity, Sensitivity analysis was used to assess the impact of

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the included trials on the final outcome. And Egger's test was performed using Stata14.0 statistical software to analyze potential publication bias. If  $P < 0.05$  was considered statistically significant.

**Subgroup analysis:** If the necessary data are available, subgroup analysis will be performed according to course.

**Sensibility analysis:** If the necessary data are available, sensibility analysis will be performed according to course.

**Language:** English.

**Keywords:** Sleep Apnea Syndrome, Huatan Huoxue prescription.

**Dissemination plans:** XXXX results of this systematic review will be disseminated through peer reviewed XXXXX.

**Contributions of each author:**

Author 1 - Min Zhou - Conceptualization.

Author 2 - Qijun Liang - Writing - review & editing.

Author 3 - Qiulan Pei - Data curation.

Author 4 - Fan Xu - Software.

Author 5 - Hang Wen - Conceptualization.