INPLASY PROTOCOL

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

Conflicts of interest:
None.

Efficacy and safety of the traditional Chinese medicine tonifying kidney (bu shen) therapy in patients with hypertension: a protocol for systematic review and meta-analysis

Tang, ZR[1]; Sun, YZ[2]; Liu, X[3]; Zhao, HB[4].

Review question / Objective: **To assess the efficacy and safety of traditional Chinese medicine tonifying kidney (bu shen) therapy in treating hypertension.**
Condition being studied: **Hypertension is an important risk factor for cardiovascular disease (CVD) worldwide, and it affects the structure and function of heart, brain, kidney and other major organs.Hypertension is increasingly becoming an alarming global health issue. Currently, many patients with hypertension apply Chinese herbal medicine as an adjuvant therapy for treating hypertension. According to Traditional Chinese Medicine theory, kidney (shen) deficiency is one of the main mechanisms of hypertension. Tonifying kidney therapy (bu shen, TKT) is widely used for the clinical treatment of hypertension, but there is no systematic review to evaluate the effectiveness and safety. Therefore, this review aims to evaluate the effectiveness and safety of TKT in the treatment of patients with hypertension.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 May 2020 and was last updated on 11 May 2020 (registration number INPLASY202050044).

INTRODUCTION

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METHODS

Participant or population: Meet the diagnostic criteria of hypertension. Participants in the review will have no restrictions on age, sex or ethnic background.

Intervention: The intervention was either TKT alone or TKT combined with conventional western medicine. We will not set limitations on dosages and course of treatment.

Comparator: Conventional western medicine.

Study designs to be included: RCTs whether use blind or not that reporting the application of TKT for patients with hypertension will be included.

Eligibility criteria: This study will include randomized controlled trials(RCTs) that explored the effect TKT for the treatment of hypertension.

Information sources: The following electronic databases will be searched from inception to June, 2020:PubMed, EMBASE, Cochrane Central Register of Controlled Trials(CENTRAL), China National Knowledge Infrastructure(CNKI), VIP Database, Chinese Biomedical Database(CBM), and Wanfang Database. Literatures must be published in English or Chinese.

Main outcome(s): 1)Systolic and diastolic blood pressure change magnitude; 2)Total efficacy rate.

Additional outcome(s): 1) Clinical symptoms; 2) Adverse events.

Data management: Two reviewers will independently screen the literature and conduct data extraction with the pre-designed data extraction table. Disagreements will be resolved by discussion and reached consensus through a third reviewer. The following data items will be extracted:the first author, publication year, diagnosis criteria, demographic information, study characteristics, interventions and controls, participants, study methodology, outcomes, adverse events, etc.

Quality assessment / Risk of bias analysis: Two reviewers will independently assess the methodological quality of included studies according to the methodology of the Cochrane Handbook version 5.1.0. The following domains will be evaluated: random sequence generation, allocation concealment, blinding method, incomplete outcome data, selective reporting, and other bias. The quality of each trial will be classified as low, high or unclear risk of bias. Disagreements will be resolved by discussion and reached consensus through a third reviewer.

Strategy of data synthesis: RevMan5.3 software will be used to analyze the results of the studies. Dichotomous data will be reported as risk ratio(RR) with corresponding 95% confidence interval (CI),whereas continuous data will be reported as the mean difference (MD) or standardized the mean difference (SMD) with corresponding 95% confidence interval (CI). The I2 test will be used to assess statistical heterogeneity. Results of the meta-analysis will be visualised by forest plots. Sensitivity and subgroup analyses will be performed to explore the potential sources of significant heterogeneity.

Subgroup analysis: If the necessary data are available, subgroup analyses will be carried out for patients. The purpose of subgroup analyses is to explore potential sources of heterogeneity.

Sensibility analysis: We will utilize a sensitivity analysis to examine the robustness of merged outcome results by removing trials with low quality.

Language: English and Chinese.

Country(ies) involved: China.

Keywords: Tonifying kidney(bu shen) therapy; hypertension; efficacy; safety.

Contributions of each author:
Author 1 - Zhuoran Tang - The author drafted the manuscript and contributed to data extraction.
Author 2 - Yize Sun - The author contributed to data extraction and quality assessment.
Author 3 - Xiang Liu - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Author 4 - Haibin Zhao - The author read, provided feedback and approved the final manuscript.