INPLASY PROTOCOL

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None declared.

Effects of Bushen Jianpi Huoxue Therapy for Treatment of Diabetic Nephropathy: A Meta-Analysis of Randomized controlled Trials

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Review question / Objective: **The aim of this systematic review is to compare Traditional Chinese Medicine:Bushen Jianpi Huoxue (BSJPHX) therapy and Western medicine in terms of efficacy and acceptability in the diabetic nephropathy to better inform clinical practice. To this end, the proposed systematic review will address the following question: Which is the best choice to reduce 24-hour urinary total protein, serum creatinine, blood urea nitrogen, fasting plasma glucose and triglyceride in Diabetic Nephropathy BSJPHX therapy or Western medicine?".**

Condition being studied: **Diabetic Nephropathies; Jianpi Bushen Huoxue Therapy.**

Eligibility criteria: **Inclusion Criteria. (1) Study type: randomized controlled trial (RCT). (2) Object of study: patients diagnosed with DN. (3) Intervention measures: control group patients with conventional comprehensive treatment, but except with BSJPHX therapy; experimental group patients with the treatment of the control group and BSJPHX therapy. (4) Outcome indicators: outcome indicators should be at least one of the following: clinical effective rate, fasting blood glucose (FBG), triglycerides(TG), 24-h urine protein quantification(UTP), serum creatinine (Scr), and blood urea nitrogen (BUN). Exclusion Criteria. (1) Languages other than Chinese or English; (2) Systematic evaluation, review, animal experiments (3) Original text cannot be obtained; (4) Not RCT or the design is not rigorous; (5) Patients with other renal diseases; (6) Intervention measures or control measures are not consistent with this study; (7) Repeated publication of data.**

1st authors* - Ziming Wang and Shasha Mei contributed equally to this study.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 March 2022 and was last updated on 20 March 2022 (registration number INPLASY202230088).

INTRODUCTION

Review question / Objective: **The aim of this systematic review is to compare Traditional Chinese Medicine:Bushen Jianpi Huoxue (BSJPHX) therapy and Western medicine in terms of efficacy and acceptability in the diabetic nephropathy to**

better inform clinical practice. To this end, the proposed systematic review will address the following question: Which is the best choice to reduce 24-hour urinary total protein, serum creatinine, blood urea nitrogen, fasting plasma glucose and triglyceride in Diabetic Nephropathy BSJPHX therapy or Western medicine?".

Condition being studied: Diabetic Nephropathies; Jianpi Bushen Huoxue Therapy.

METHODS

Participant or population: Male or female enrolled in studies of diabetic nephropathy screening will be eligible for this review, with no exclusions based on ethnicity or age.

Intervention: Control group patients with conventional comprehensive treatment, but except with BSJPHX therapy; experimental group patients with the treatment of the control group and BSJPHX therapy.

Comparator: Patients in the control group were given conventional western medicines alone.

Study designs to be included: All published RCTs that meet the requirements.

Eligibility criteria: Inclusion Criteria. (1) Study type: randomized controlled trial (RCT). (2) Object of study: patients diagnosed with DN. (3) Intervention measures: control group patients with conventional comprehensive treatment, but except with BSJPHX therapy; experimental group patients with the treatment of the control group and BSJPHX therapy. (4) Outcome indicators: outcome indicators should be at least one of the following: clinical effective rate, fasting blood glucose (FBG), triglycerides(TG), 24-h urine protein quantification(UTP), serum creatinine (Scr), and blood urea nitrogen (BUN). Exclusion Criteria. (1) Languages other than Chinese or English; (2) Systematic evaluation, review, animal experiments (3) Original text cannot be obtained; (4) Not RCT or the design is not rigorous; (5) Patients with other renal diseases; (6) Intervention measures or control measures are not consistent with this study; (7) Repeated publication of data.

Information sources: Seven different databases (China National Knowledge Infrastructure, Wanfang Database, VIP, China Biological Medicine Database, PubMed, Cochrane Library and Embase) were independently searched from inception to February 2022.

Main outcome(s): Clinical effective rate, fasting blood glucose (FBG), triglycerides (TG), 24-h urine protein quantification(UTP), serum creatinine (Scr), and blood urea nitrogen (BUN).

Quality assessment / Risk of bias analysis: The Cochrane Risk Bias Assessment Tool was used as the standard for rigorous evaluation as following aspects: (1) method of random allocation and allocation concealment; (2) blinding method of participants and personnel; (3) blinding method of outcome assessment; (4) selectivity of result reporting; (5) other biases.

Strategy of data synthesis: RevMan 5.4 was performed to data analyses. Relative risk (RR) was used as the effect size for dichotomous outcomes. Mean difference (MD) was used as the effect size for continuous outcomes with 95% confidence interval (CI) . Q test and I 2 test were used to assess heterogeneity. If P>0.10 and I 2<50%, the fixed-effect model was applied; if not, the random effect model was applied.

Subgroup analysis: There are some planned subgroup analyses that will be performed: different specific therapies included in the tonifying-kidney, strengthening-spleen and invigorating-blood circulation (bushen-jianpi-huoxue) principle, different kinds of treatment methods (traditional Chinese herbal medicine, acupuncture and moxibustion combined with traditional Chinese herbal medicine, acupoint catgut embedding, and

acupoint injection), different treatment periods and different follow-up periods (≤3 months, 3-6 months, >6 months).Sensitivity analysis was carried out to find the source of heterogeneity. Further subgroup analyses were applied to heterogeneity determine clinical study and methodology. P<0.05 was considered as statistically significant difference.

Sensitivity analysis: Sensitivity analysis was carried out to find the source of heterogeneity. Further subgroup analyses were applied to heterogeneity determine clinical study and methodology. P<0.05 was considered as statistically significant difference.

Language: Only randomized clinical trials published in English and Chinese will be considered for inclusion.

Country(ies) involved: China.

Keywords: Diabetic Nephropathy, Bushen Jianpi Huoxue Therapy, Meta-Analysis, Randomized controlled Trial.

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