INPLASY PROTOCOL

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Conflicts of interest:
This work has no conflicts of interest.

Baihu Jia Renshen Decoction for Type 2 Diabetic Mellitus: A Protocol for Systematic Review and Meta-analysis

Tian, Y[1]; Xie, X[2].

ABSTRACT

Objective: This review aims to systematically evaluate the benefits and harms of BJRD for T2DM patients reported in randomized clinical trials (RCTs).

Condition being studied: Diabetes is a metabolic disorder caused by insulin deficiency and / or insulin dysfunction, which is characterized by chronic hyperglycemia. At present, about 415 million people in the world suffer from diabetes, of which more than 90% are type 2 diabetes, which causes severe physical and mental pain to patients and their families, and also imposes a huge burden on the health care system.

Information sources: A This review will include grey literature sourced from CCPD (China Conference Paper Database), manual searching. Electronic database includes PubMed, Embase, Cochrane Library, Web of Science, CNKI, WanFang, VIP and CBM will also be searched.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 April 2020 and was last updated on 02 April 2020 (registration number INPLASY202040006.

INTRODUCTION

Objectives / Review question: This review aims to systematically evaluate the benefits and harms of BJRD for T2DM patients reported in randomized clinical trials (RCTs).

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diabetes, of which more than 90% are type 2 diabetes, which causes severe physical and mental pain to patients and their families, and also imposes a huge burden on the health care system.

METHODS

Participant or population: The patients of type 2 diabetes (using WHO1999 diagnostic criteria). These types of patients will not be included: patients with acute complications of diabetes; patients with severe heart disease, liver and kidney dysfunction, mental illness, or a relevant drug allergic history and patients during pregnancy or lactation.

Intervention: Conventional diabetes treatments recommended by the ADA guidelines, including diet, exercise, and hypoglycemic and lipid-lowering therapies and Baihu Jia Renshen Decoction or modified Baihu Jia Renshen Decoction.

Comparator: Conventional diabetes treatments and placebo or conventional treatments only.

Study designs to be included: Only randomized controlled trial will be included.

Eligibility criteria: Only RCTs (except Quasi-RCTs and cluster RCTs) will be included. Animal mechanism studies and non-randomised clinical trials will be excluded. Article that substantially overlaps with another published article in print or electronic media will be excluded. Duplicate publications produced by a single experiment and published as separate papers with different criteria for measuring results, priority will be given to original publications and other publications will be excluded. The language and time of publication will not be restricted.

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Main outcome(s): The primary outcomes include 2h plasma glucose, Fasting plasma glucose, Hemoglobin A1c, homeostasis model assessment of insulin resistance and fasting plasma insulin.

Additional outcomes: The secondary outcomes include clinical efficacy and adverse events. The clinical efficacy refers to the guiding principles for clinical research of new Chinese medicines [26] and is determined according to the degree of improvement of the symptoms of the patient before and after treatment: markedly effective: symptoms improved significantly more than 70%; effective: symptoms reduced by 30% to 70%; Ineffective: Symptom improvement is less than 30% or no improvement, or even worse.

Quality assessment / Risk of bias analysis: All the included studies will be evaluated based on the guidelines of Cochrane Handbook for Systematic Reviews of Interventions . The quality of each trial will be categorized into 'low', 'unclear', or 'high' risk of bias according to the following items: adequacy of generation of the allocation sequence, allocation concealment, blinding of participants and personal, blinding of outcome assessors, incomplete outcome data, selected reporting the results and other sources of bias (such as comparable baseline characteristic, inclusion and exclusion criteria).

Strategy of data synthesis: We used Revman 5.3 software provided by the Cochrane collaboration to analyze the data. Binary outcomes will be summarized using risk ratio (RR) with 95% confidence interval (CI) for relative effect. Continuous outcomes will be summarized by using weighted mean difference (WMD) with 95% CI. We will use random-effect model (REM) for meta-analysis in this review according to research recommendations. Statistical heterogeneity will be assessed by X^2 and I2 statistical tests. Where p value ≥0.1and I2 ≤50%, there is no obvious statistical heterogeneity among the studies. On the contrary, where p value 50% indicates a

considerable heterogeneity. Meta-analysis will be performed when the statistical heterogeneity is acceptable (p value ≥0.1and I2 ≤50%), otherwise, subgroup analysis will be applied to explore the influence of potential factors on the outcome measures.

Subgroup analysis: We will conduct Subgroup analyses by different race, age, gender, course of treatment, and different type of Baihu Jia Renshen Decoction (intervention forms, pharmaceutical dosage form, dosage, etc). If a meta-analysis cannot be performed, we will conduct descriptive analysis instead.

Sensibility analysis: We will conduct sensitivity analyses by omitting studies one by one to probe the impact of an individual study.

Language: China.

Keywords: Baihu Jia Renshen Decoction; Type 2 Diabetes Mellitus; Systematic review.