

INPLASY PROTOCOL

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None declared.

Effectiveness of Xiaoyao Decoction in the treatment of Diabetes mellitus with depression: a protocol for systematic review and meta-analysis

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Review question / Objective: 1. Type of studies. This study will include all relevant randomized clinical trials (RCTs) without language restrictions. 2. Type of participants. The patient was clinically diagnosed with type 2 diabetes and depression, manifested as low self-esteem, pain, pessimism, misogyny, etc., high glycosylated hemoglobin values, or glycosylated hemoglobin in the normal range after drug treatment. The patients were regardless of age, sex or race. 3. Type of interventions. XYD is used in the treatment of Diabetic patients with depression in the form of decoction, powder, capsule and so on. 4. Type of comparators. Oral routine western medicine with variable dosage form. 5. Types of outcome measures. The total effective rate of clinical remission, the self rating depression scale (SDS) score, the symptom Checklist 90 (SCL-90) score, the levels of Fasting glucose, postprandial glucose, glycosylated hemoglobin, BMI.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 September 2022 and was last updated on 21 September 2022 (registration number INPLASY202290103).

INTRODUCTION

Review question / Objective: 1. Type of studies. This study will include all relevant randomized clinical trials (RCTs) without language restrictions. 2. Type of participants. The patient was clinically diagnosed with type 2 diabetes and depression, manifested as low self-esteem,

pain, pessimism, misogyny, etc., high glycosylated hemoglobin values, or glycosylated hemoglobin in the normal range after drug treatment. The patients were regardless of age, sex or race. 3. Type of interventions. XYD is used in the treatment of Diabetic patients with depression in the form of decoction, powder, capsule and so on. 4. Type of

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Condition being studied: Clinically significant depression is present in one of every four people with type 2 diabetes mellitus(T2DM). Depression increases the risk of the development of T2DM and the subsequent risks of hyperglycemia, insulin resistance, and micro- and macrovascular complications. Conversely, a diagnosis of T2DM increases the risk of incident depression and can contribute to a more severe course of depression. This linkage reflects a shared etiology consisting of complex bidirectional interactions among multiple variables. Therefore, the same treatment of different diseases has a key role. Traditional Chinese medicine (TCM) has the characteristics of multi-target therapy. Xiaoyao Decoction(XYD) has a good effect on soothing the liver and relieving depression, which may be a promising choice for the treatment of diabetes with depression.

METHODS

Participant or population: The patient was clinically diagnosed with type 2 diabetes and depression, manifested as low self-esteem, pain, pessimism, misogyny, etc., high glycosylated hemoglobin values, or glycosylated hemoglobin in the normal range after drug treatment. The patients were regardless of age, sex or race.

Intervention: XYD is used in the treatment of Diabetic patients with depression in the form of decoction, powder, capsule and so on.

Comparator: Oral routine western medicine with variable dosage form.

Study designs to be included: This study will include all relevant randomized clinical trials (RCTs) without language restrictions.

Eligibility criteria: 1. Type of studies. This study will include all relevant randomized clinical trials (RCTs) without language restrictions. 2. Type of participants. The patient was clinically diagnosed with type 2 diabetes and depression, manifested as low self-esteem, pain, pessimism, misogyny, etc., high glycosylated hemoglobin values, or glycosylated hemoglobin in the normal range after drug treatment. The patients were regardless of age, sex or race. 3. Type of interventions. XYD is used in the treatment of Diabetic patients with depression in the form of decoction, powder, capsule and so on.4.Type of comparators. Oral routine western medicine with variable dosage form.5. Types of outcome measures. The total effective rate of clinical remission, the self rating depression scale(SDS) score, the symptomChecklist90(SCL-90) score, the levels of Fasting glucose, postprandial glucose, glycosylated hemoglobin, BMI.

Information sources: RCTs of BXD for gastric precancerous lesions will be searched in the relevant database, including PubMed, Embase, Cochrane Library, China National Knowledge Infrastructure (CNKI), Wanfang Database, Chinese Biomedical Literature Database (CBM) and Chinese Scientific Journal Database (VIP database). The studies of electronic searches will be exported to EndNote V.9.1 software. We will run meta-analyses using the Review Manager (RevMan) V.5.3 software. Any disagreement will be solved in consultation with a third reviewer.

Main outcome(s): The total effective rate of clinical remission, the self rating depression scale(SDS) score, the symptomChecklist90(SCL-90) score, the levels of Fasting glucose, postprandial glucose, glycosylated hemoglobin, BMI.

Data management: We will establish a data extraction table, which will be used by 2 researchers to extract data from qualified literature. The specific contents will include: author, publication time, participant characteristics, intervention (s), comparison (s), outcome (s), adverse

events and some relevant features. If the significant information of the article is incomplete, we will contact the author. In case of disagreements, the third researcher will be consulted.

Quality assessment / Risk of bias analysis:

The Cochrane risk assessment tool will be used by us to evaluate the methodological quality of qualified RCTs. It includes 7 items: random sequence generation, allocation concealment, blinding of participants and caregivers, blinding of outcome assessors, incomplete outcome data, selective outcome reporting, and other bias. The evaluation result of each item will be “high risk”, “low risk”, or “unclear risk”. The assessment will be completed by 2 reviewers, and disagreements will be handed over to the third reviewer for the final decision.

Strategy of data synthesis: Data synthesis will be completed using RevMan5.3.5 software. When $I^2 < 50\%$, we will choose the fixed effects model; Otherwise, the random effects model will be selected. The forest plots will present the results of the metaanalyses. We will conduct descriptive analysis, when the results are not suitable for consolidation. When more than 10 studies are included, we will use the funnel plot to assess publication bias.

Subgroup analysis: If necessary, subgroup analyses will be performed according to the different types of participant characteristics, treatment methods, treatment frequency, and so on.

Sensitivity analysis: When there is significant heterogeneity, we will conduct a sensitivity analysis. We will determine the robustness of the results by excluding low quality studies.

Country(ies) involved: China.

Keywords: Diabetes; Depression; Xiaoyao Decoction; protocol.

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