INPLASY PROTOCOL

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Comparative efficacy and safety of traditional Chinese patent medicine for Cognitive dysfunction in Diabetic cognitive dysfunction A protocol for systematic review and Bayesian network meta-analysis

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Review question / Objective: **1. There are many kinds of Chinese patent medicines for the treatment of diabetic cognitive dysfunction, how to evaluate their effectiveness and safety? 2. In the published meta-analysis, what is the effectiveness and safety of Chinese patent medicines for the treatment of diabetic cognitive dysfunction?**
Condition being studied: **There are many kinds of Chinese patent medicines for the treatment of this disease. The network meta-analysis can compare the efficacy and safety of different Chinese patent medicines in the treatment of diabetic cognitive dysfunction, and provide comprehensive and conclusive evidence. Compared with traditional meta-analysis, it has obvious advantages. Can provide reliable evidence for clinical decision-making.**

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INTRODUCTION

Review question / Objective: **1. There are many kinds of Chinese patent medicines for the treatment of diabetic cognitive dysfunction, how to evaluate their effectiveness and safety? 2. In the published meta-analysis, what is the effectiveness and safety of Chinese patent**

medicines for the treatment of diabetic cognitive dysfunction?

Condition being studied: There are many kinds of Chinese patent medicines for the treatment of this disease. The network meta-analysis can compare the efficacy and safety of different Chinese patent medicines in the treatment of diabetic cognitive dysfunction, and provide comprehensive and conclusive evidence. Compared with traditional meta-analysis, it has obvious advantages. Can provide reliable evidence for clinical decision-making.

METHODS

Participant or population: Patients with diabetic cognitive dysfunction treated with Chinese patent medicine.

Intervention: The experimental group was treated with traditional Chinese medicine combined with conventional Western medicine, including Xiaoke Pill, Jinqi Jiangtang Tablet, Yuquan Capsule, Qizhi Jiangtang Capsule, etc.; the control group received conventional Western medicine treatment, including oral medication or insulin injection. RCTs that use two or more proprietary Chinese medicines or combined acupuncture, moxibustion and other traditional Chinese medicine methods are excluded.

Comparator: Any other treatment (e.g.,Western medicine)mentioned in included meta-analyses.

Study designs to be included: We will include published English and Chinese meta-analyses focusing on Traditional Chinese patent medicine for diabetes cognitive dysfunction.

Eligibility criteria: We will include all RCTs that use proprietary Chinese medicines to treat diabetic cognitive dysfunction, as well as related clinical trials, for example, I/II early stage, stage III trial, prospective and retrospective observational studies; we will exclude meta-analysis, case reports, and studies with insufficient data. The language is limited to Chinese and English.

Information sources: We will search PubMed, Cochrane Library, ClinicalTrials, Embase, CNKI database, Weipu database, Wanfang database, China Biomedical Database. The Chinese search terms are "diabetic cognitive dysfunction", "diabetic cognitive dysfunction", "diabetic dementia", "Chinese patent medicine", and "randomized controlled trial". The English search terms are "traditional Chinese patent medicine", "TCPM", "Diabetic cognitive dysfunction", "Diabetic cognitive impairment", "Randomized controlled". The search time limit is from the establishment of each database to September 2021.

Main outcome(s): According to the Montreal Cognitive Assessment Scale (MoCA), a 5-level scoring method of 0-4 points is adopted. The main indicators are: total clinical effectiveness, blood glucose stability, and improvement of cognitive function. Secondary indicators include relapse rate, The degree of stability of glycosylated hemoglobin and the improvement rate of visual space function. The included literature must cover one or more main indicators.

Quality assessment / Risk of bias analysis: The quality of each trial will be assessed by two researchers independently based on the Cochrane Risk of Bias Risk Assessment Tool recommended by Cochrane Handbook version 5.1.0. Use the decision words "high risk", "low risk", and "unclear risk" to evaluate the quality of the input article in 7 aspects, including: whether the random sequence is sufficient; whether there is hidden allocation; whether blinding is used; whether the result data is complete; Whether there is selective reporting; whether there is publication bias; others.

Strategy of data synthesis: We will use Stata 14.0 software and Markov chain-Monte Carlo (MCMC) method to conduct Bayesian meta-analysis. Three Markov chains will be used for simulation, and the number of iterations will be set at 50,000

(the first 20,000 are used for annealing to eliminate the effect of the initial value, and the last 30,000 are used for sampling). The reticular diagram will be drawn by Stata 15.0 software to show the direct and indirect comparison between different interventions. The relative odds ratio (RoR) and its 95% confidence interval (CI) are calculated to evaluate the consistency of each closed loop. The lower limit of 95% CI is equal to 1, indicating good consistency. If RoR is close to 1, direct evidence and indirect evidence are consistent, and the fixed effect model is adopted for analysis. Otherwise, the closed-loop is considered to have obvious inconsistencies, and the random effect model is used for analysis. Dichotomous data will be represented by odds ratio (OR) and 95% CI, and P<.05 was considered statistically significant. WinBUGS 1.4.3 will be used to rank the efficacy of different interventions and the area under the curve will be recorded (the area under the curve will be expressed as a percentage, the larger the value, the better the effect).

Subgroup analysis: If the information is sufficient, subgroup analysis will be considered.

Sensitivity analysis: Sensitivity analysis will be conducted with symptom improvement rate to evaluate clinical similarity and methodology of included studies to determine the reliability of the results of this study.

Country(ies) involved: China.

Keywords: Traditional Chinese patent medicine (TCPM),Diabetes cognitive dysfunction, Network meta-analysis, Protocol.

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