

INPLASY PROTOCOL

To cite: Peng et al. The efficacy of five-element therapy for senile diabetes with depression: Protocol for a systematic review and meta-analysis. Inplasy protocol 2020100081. doi: 10.37766/inplasy2020.10.0081

Received: 22 October 2020

Published: 22 October 2020

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Support: NO. 2019YFS0380.

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

Conflicts of interest:
No conflict of interest.

The efficacy of five-element therapy for senile diabetes with depression: Protocol for a systematic review and meta-analysis

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Review question / Objective: P:Participants diagnosed as diabetes with depression (aged \geq 60 years) will be included. All participants will regardless of gender and ethnicity. I:This meta-analysis will include the RCTs of five-element therapy regardless of duration and frequency. C:Conventional treatment according to relevant guideline, or other forms of Chinese traditional non-drug intervention such as Tai Chi, acupuncture, Tuina, etc. O:The primary outcomes of this review are fasting blood glucose (FBG)and two hour postprandian blood glucose (2hPG).The secondary outcomes include the following items: HbA1c, fasting insulin (FINS), homeostasis model assessment of insulin resistance (HOMA-IR), quantitative insulin sensitivity check index (QUICKI). S:meta-analysis.

Condition being studied: Senile diabetes with depression.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 October 2020 and was last updated on 22 October 2020 (registration number INPLASY2020100081).

INTRODUCTION

Review question / Objective: P:Participants diagnosed as diabetes with depression (aged \geq 60 years) will be included. All participants will regardless of gender and ethnicity. I:This meta-analysis will include the RCTs of five-element therapy

regardless of duration and frequency. C:Conventional treatment according to relevant guideline, or other forms of Chinese traditional non-drug intervention such as Tai Chi, acupuncture, Tuina, etc. O:The primary outcomes of this review are fasting blood glucose (FBG)and two hour postprandian blood glucose (2hPG).The

secondary outcomes include the following items: HbA1c, fasting insulin (FINS), homeostasis model assessment of insulin resistance (HOMA-IR), quantitative insulin sensitivity check index (QUICKI). S:meta-analysis.

Condition being studied: Senile diabetes with depression.

METHODS

Search strategy: The literature search will be performed by using the following databases: Pubmed, Embase, Cochrane Library, Web of science, Chinese National Knowledge Infrastructure (CNKI), Wanfang Databas, Sino Med, China Biomedical Literature Database (CBM). Studies published from the inception to October 2020 without language restrictions. The search strategy will be developed by the research team in collaboration with an experienced librarian and checked by a referee according to the Peer Review of Electronic Search Strategy guidelines.

Participant or population: Participants diagnosed as diabetes with depression (aged ≥ 60 years) will be included.

Intervention: This meta-analysis will include the RCTs of five-element therapy regardless of duration and frequency.

Comparator: Conventional treatment according to relevant guideline, or other forms of Chinese traditional non-drug intervention such as Tai Chi, acupuncture, Tuina, etc.

Study designs to be included: Randomized controlled clinical trials and quasi-randomized controlled trials will be considered for inclusion in this study. Studies involving non-RCTs, reviews, animal experiments, case series will be excluded.

Eligibility criteria: Randomized controlled clinical trials and quasi-randomized controlled trials will be considered for inclusion in this study.

Information sources: The literature search will be performed by using the following databases: Pubmed, Embase, Cochrane Library, Web of science, Chinese National Knowledge Infrastructure (CNKI), Wanfang Databas, Sino Med, China Biomedical Literature Database (CBM).

Main outcome(s): The primary outcomes of this review are fasting blood glucose (FBG) and two hour postprandial blood glucose (2hPG). The secondary outcomes include the following items: HbA1c, fasting insulin (FINS), homeostasis model assessment of insulin resistance (HOMA-IR), quantitative insulin sensitivity check index (QUICKI).

Quality assessment / Risk of bias analysis: Two investigators will independently assess the risk of bias according to the Cochrane Handbook for Systematic Reviews of Interventions. The following seven items should be contained, such as random sequence generation, allocation concealment, blinding of participants and personnel, the blindness of outcome assessments, incomplete outcome data, selective outcome reporting, and other biases. The results will be checked repeatedly and the differences will be resolved by further discussion of all reviewers.

Strategy of data synthesis: We will utilize the Review Manage software V5.3.0 to analyze all data. And we will calculate the risk ratio (RR) for dichotomous with 95% confidence intervals (CIs). For continuous data, mean difference (MD) will be included in the meta-analysis. While the outcome variables are measured by different scales, standard mean differences (SMD) analysis with 95% CI will be estimated in the meta-analysis as well.

Subgroup analysis: We will analyze subgroups based on different frequency and duration of the five-element therapy.

Sensibility analysis: We will conduct sensitivity analysis, meta-regression and subgroup analysis based on the various study characteristics and samples. For

example, the study type, study quality as well as the adjustment for confounders are included in. A brief qualitative analysis of the evidence will be presented in narrative form if data extraction is insufficient or significant differences exist in study methods.

Country(ies) involved: China.

Keywords: Senile diabetes with depression, five-element therapy, meta-analysis, protocol, systematic review.

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