INPLASY PROTOCOL

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Ginseng-plus-Bai-Hu-Tang combined with western medicine for the treatment of Type 2 Diabetes Mellitus: A protocol for Systematic Review and Meta-Analysis

Zhou, M[1]; Yu, R[2]; Liu, X[3]; Xiang, Q[4]; Lv, X[5].

Review question / Objective: In order to verify effectiveness and safety of GBHT combined with CWM in the treatment of T2DM, we carried out this meta-analysis.

Information sources: We selected all clinical trials of GBHT combined with CWM for the treatment of T2DM. After extensive searches on various websites from their establishment to September 1, 2021, including EMBASE, PubMed, the China Science and Technology Journal Database (VIP), the Chinese Biomedical Literature Database (CBM), the Cochrane Library, the China National Knowledge Infrastructure(CNKI), and the WanFang databases, target literatures were picked out. Manual searches would also be performed to track necessary references on related literature. Two independent researchers(Min Zhou and Xiu Liu) conducted extensive screening and extracted target-related data from them for classification and integration. The extracted data included the first author, publication year, baseline characteristics, intervention, outcome indicators, and adverse events. In the process of screening, if we encounter difficulties that are difficult to resolve, we would to discuss and decide in detail with the third researcher(Rong Yu).

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 January 2022 and was last updated on 01 January 2022 (registration number INPLASY202210003).

INTRODUCTION

Review question / Objective: In order to verify effectiveness and safety of GBHT combined with CWM in the treatment of T2DM, we carried out this meta-analysis.

Rationale: We performed the meta-analyses with the help of RevMan 5.3.3 and stata 12.0 software. Among them, odds ratio(OR) was used to evaluate binary variables, and mean difference (MD) was

adopted to evaluate continuous variables. If it was less than 0.5, there was statistically significant, and vice versa. Heterogeneity was adopted to evaluate the effect, if P>0.1 or I2<50%, the result was considered to be non-heterogeneity, the fixed effects model was adopted, otherwise, the random effects model was adopted. Finally, sensitivity analysis would be conducted on each indicator to evaluate the stability, and the Egger test would be performed to test potential publication bias. Similarly, P<0.05 would be considered meaningful.

Condition being studied: A total of 381 potential literatures were selected after extensive browsing and collection. 172 studies remained after we excluded 209 duplicates. And we excluded 118 literatures that did not meet the research objects by screening the title and abstract of the literature in detail. Immediately after that, we deleted 42 literatures based on the inclusion criteria, and finally, we screened out 12 studies that met the inclusion criteria.

METHODS

Search strategy: "Jingfang" OR "traditional Chinese medicine"OR "Integrated treatment of TCM and CWM" OR"ginseng-plus-Bai-Hu-Tang"AND"Diabetes Mellitus" OR "Diabetes Mellitus type 2" OR "T2DM" OR "DM(監)" OR "Xiaoke" OR "Xiaodan"OR "Pidan"AND"randomized controlled trial" OR "randomize trial"OR"clinical research"" randomized"OR"trial".

Participant or population: Type of patients: the patients were diagnosed with T2DM, regardless of race, nationality, gender, age, or course of disease.

Intervention: Types of intervention: the experimental group was treated with GBHT combined with CWM.

Comparator: The control group was treated with CWM alone.

Study designs to be included: Study type: the included studies were RCTs studying GBHT combined with CWM for treating T2DM.

Eligibility criteria: (1)Non-RCTs and duplicate literatures.(2)Mechanism research, animal experiments, experience, and case reports.

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Main outcome(s): Types of outcome measures: the primary outcomess included the effective rate.

Additional outcome(s): Fasting blood glucose(FBG), 2 hours postprandial blood glucose (2hBG), glycated hemoglobin (HbA1c). The secondary outcomes were fasting insulin (FINS),Homeostasis model assessment of insulin resistance (HOME-RI).

Data management: We performed the meta-analyses with the help of RevMan 5.3.3 and stata 12.0 software. Among them, odds ratio(OR) was used to evaluate binary variables, and mean difference (MD) was

adopted to evaluate continuous variables. If it was less than 0.5, there was statistically significant, and vice versa. Heterogeneity was adopted to evaluate the effect, if P>0.1 or I2<50%, the result was considered to be non-heterogeneity, the fixed effects model was adopted, otherwise, the random effects model was adopted. Finally, sensitivity analysis would be conducted on each indicator to evaluate the stability, and the Egger test would be performed to test potential publication bias. Similarly, P<0.05 would be considered meaningful.

Quality assessment / Risk of bias analysis: Based on the Cochrane Systematic Review Manual RCT bias risk assessment tool, we completed the risk assessment of the included studies. The contents include the following: (1)random sequence generation, (2) allocation concealment, (3) blinding of participants and personnel, (4) blinding of outcome assessment, (5) incomplete outcome data, (6) selective reporting, and (7) other bias.

Strategy of data synthesis: The following were the search keywords and terms we used:"Jingfang" OR "traditional Chinese medicine"OR "Integrated treatment of TCM and CWM" OR"ginseng-plus-Bai-Hu-Tang" AND"Diabetes Mellitus" OR "Diabetes Mellitus type 2" OR "T2DM" OR "DM⟮䚍⟯" OR "Xiaoke" OR "Xiaodan"OR "Pidan" AND"randomized controlled trial"OR "randomize trial"OR"clinical research"" randomized"OR"trial".

Subgroup analysis: If necessary, we will do subgroup analysis.

Sensitivity analysis: If necessary, we will do Sensitivity analysis.

Language: English.

Country(ies) involved: China The US.

Other relevant information: The authors declare that they have no conflicts of interest.

Contributions of each author:
Author 1 - Min Zhou.
Author 2 - Rong Yu.
Author 3 - Xiu Liu.
Author 4 - Qin Xiang.
Author 5 - Xialin Lv.