INPLASY PROTOCOL

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The Effect of Traditional Chinese Medicine Combined with Metformin Therapy on Gut Microbiota Abundances in Middle-aged and Elderly Patients with Type 2 Diabetes Mellitus: A Systematic Review and Meta-Analysis

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Review question / Objective: **No prior scientific study has demonstrated how metformin and traditional Chinese medicine (TCM) can be combined to regulate the abundances of gut microbiota in middle-aged and older individuals with type 2 diabetes mellitus (T2DM). In this research, we conducted a meta-analysis to analyse the changes in abundance of various gut microbiota species after combined therapy with TCM and metformin compared to metformin alone in middle-aged and older adults to provide a rationale for gut microbiota as a therapeutic target in T2DM.**
Background: **Type 2 diabetes mellitus (T2DM) is a chronic metabolic disease characterised by elevated blood glucose levels as the main clinical manifestation; it is caused by genetic or environmental factors and leads to absolute or relative insufficiency of insulin secretion or dysfunction of insulin action in the body . If the symptoms of T2DM are not effectively controlled, the disease continues to develop, which causes complications such as cardiovascular and cerebrovascular diseases, retinopathy, and diabetic nephropathy.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 March 2023 and was last updated on 23 March 2023 (registration number INPLASY202330087).

INTRODUCTION

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compared to metformin alone in middle-aged and older adults to provide a rationale for gut microbiota as a therapeutic target in T2DM.

Background: Type 2 diabetes mellitus (T2DM) is a chronic metabolic disease characterised by elevated blood glucose levels as the main clinical manifestation; it is caused by genetic or environmental factors and leads to absolute or relative insufficiency of insulin secretion or dysfunction of insulin action in the body . If the symptoms of T2DM are not effectively controlled, the disease continues to develop, which causes complications such as cardiovascular and cerebrovascular diseases, retinopathy, and diabetic nephropathy .

Rationale: Conventional Western medicine primarily uses hypoglycaemic drugs such as metformin to treat T2DM, but long-term use has been linked to toxicity and various side effects. 10, 14According to traditional Chinese medicine (TCM), diabetes is classified as Xiao Ke and mainly divided into four types: deficiency of qi and yin, excess of heat due to yin deficiency, internal resistance of blood stasis, and deficiency of yin and yang.Among them, the symptoms of qi and yin deficiency are the most common and clinically manifest as fever and night sweats, thirst, and shortness of breath .19 Although TCM was recently shown to offer certain advantages in regulating the blood sugar levels of patients and reducing adverse reactions,21 no evidence-based reports are available on the effects of TCM in combination with metformin on the gut microbiota of middle-aged and older adults with type 2 diabetes. In this research, a meta-analysis was conducted to analyse changes in the abundances of gut microbiota in middle-aged and older people after receiving combined TCM and metformin therapy for T2DM, to provide support for the gut microbiota as a therapeutic target in T2DM.

METHODS

Strategy of data synthesis: We searched the PubMed, Embase, Cochrane Library, CNKI, Wanfang, CQVIP, and CBM databases from inception through September 2022 for randomised controlled trials that used TCM in combination with metformin to treat elderly and middle-aged T2DM patients.

Eligibility criteria: Research object: Patients with T2DM who are middle-aged orelderly.

Source of evidence screening and selection: We searched the PubMed, Embase, Cochrane Library, CNKI, Wanfang, CQVIP, and CBM databases from inception through September 2022, using the following search terms: ('type 2 diabetes' or 'type 2 diabetes mellitus' or 'T2D' or 'T2DM') and ('gut microbiota' or 'gastrointestinal microbiome' or 'gut flora' or 'dysbiosis' or 'eubiosis') and ('conventional Chinese medicine' or 'TCM' or 'Chinese herbal medicine' or 'Chinese medicinal herb' or 'Chinese patent medicine' or 'Chinese herbal compound prescription') and ('randomised controlled trial' or 'controlled clinical trial' or 'RCT').

Data management: Two researchers independently conducted the literature search, screening, and information retrieval. The choice to include or exclude studies was made after consultation with a third party when there were questions or differences of opinion. The authors, publication year, study design, number of cases, and outcome indicators were included in the extracted information.

Language restriction: No Language restriction.

Country(ies) involved: China.

Keywords: conventional Chinese medicine; metformin; gut microbiota; middle-aged and elderly; type 2 diabetes mellitus.

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