

INPLASY PROTOCOL

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None declared.

Traditional Chinese Medicine Constitution Correlated with pre- diabetes mellitus: A Systematic Review and Meta-Analysis

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Review question / Objective: In this study, a systematic review and meta-analysis of the clinical research literature on TCM constitution of pre-DM was carried out, in order to obtain a larger sample data, discover the types of TCM constitution prone to pre-DM, and provide evidence-based medicine for clinical and scientific research.

Condition being studied: According to the research report of International Diabetes Federation (IDF) and American Diabetes Association (ADA), pre-DM is an inevitable stage of type 2 diabetes mellitus (T2DM) and a huge reserve army for T2DM. The number of DM patients in the world was up to 425 million in 2017, and is expected to reach 629 million in 2045; The global pre-DM population was estimated at 280 million, which is expected to increase to 396 million by 2025. The prevalence of DM in China is 10.9 percent, the highest in the world; The prevalence of pre-DM is increasing yearly, and the growth rate is as high as 35.7%. The pre-DM population increases an individual's absolute risk of developing DM by 3-10 times, with approximately 9% of the pre-DM population developing DM within an average of 34 months. In addition, pre-DM is also considered to be a high risk factor for cardiovascular disease, stroke and related death.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 January 2022 and was last updated on 28 January 2022 (registration number INPLASY202210130).

INTRODUCTION

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METHODS

Search strategy: Clinical studies on the correlation between constitution and pre-DM were searched in China National Knowledge Infrastructure (CNKI), Chongqing VIP database (CQ-VIP), Wang Fang database, Chinese Biomedical Literature Database (CMB), PubMed, Embase, The Cochrane Library, and Web of Science from April 2009 (the Constitution in Chinese Medicine Questionnaire's publication time) to January 1, 2022. The search terms included "pre-diabetes mellitus," "decreased glucose tolerance," "impaired fasting glucose," "impaired glucose regulation," "tangniaobingqianqi" (Chinese pinyin of pre-DM), "constitution," or "physique," "tizhi" (Chinese pinyin of constitution). No restrictions on nationality, language and publication. As an example on one specific strategy, the search terms for PubMed were as follows #1: pre-diabetes mellitus; #2: decreased glucose

tolerance; #3: impaired fasting glucose; #4: impaired glucose regulation; #5: constitution; #6: #1 OR #2 OR #3 OR #4 AND #5 Filters: Humans from 2009 to 2022.

Participant or population: Inclusion: the research objects with pre-diabetes mellitus (as diagnosed using any recognised diagnostic criteria). Exclusion: the basic information of research object was not reported (gender, age and region, etc.)

Intervention: The system review and meta-analysis will be focus on the correlation between TCM constitution and pre-diabetes mellitus.

Comparator: TCM constitutions control each other.

Study designs to be included: All clinical studies (including cross-sectional studies, case-control studies and cohort studies, etc.) in Chinese or English on the correlation between TCM constitution and pre-DM are included.

Eligibility criteria: Inclusion. (1) Research object: the research object is pre-DM population with definite diagnosis; (2) Research type: all clinical studies (including cross-sectional studies, case-control studies and cohort studies) in Chinese or English on the correlation between TCM constitution and pre-DM are included; (3) Research tools: The measurement tool used for constitution identification subjects is the standard of Classification and Evaluation Criteria of TCM Constitution promulgated by the China Association of Chinese Medicine (CACM) in 2009. (4) The sample size of the study is clear and the constitution data is complete. Exclusion. (1) study lacking basic information reports or statistics on constitution composition; (2) the included research subjects were associated with other systemic serious diseases that might affect their TCM constitution types; (3) this study is limited to a certain type of constitution, such as simple phlegm-dampness constitution study; (4) repeated publication of research

data; (5) review, comment or case report; (6) the full text is not available.

Information sources: China National Knowledge Infrastructure (CNKI), Chongqing VIP database (CQ-VIP), Wang Fang database, Chinese Biomedical Literature Database (CMB), PubMed, Embase, The Cochrane Library, and Web of Science.

Main outcome(s): Meta-Analysis of Distribution of TCM Constitution in pre-diabetes mellitus.

Quality assessment / Risk of bias analysis: The Newcastle-Ottawa Scale (NOS) was used to assess the methodological quality of cohort study and case-control study. The scale was compared with eight items from three aspects: selection of research population, comparability between groups and measurement of exposure factors, with a total score of 9 points, and scores over 6 points are considered to be of high quality. The cross-sectional study adopted the standards recommended by the Agency for Healthcare Research and Quality (AHRQ), for Quality evaluation, which was divided into 11 items, including data sources, inclusion criteria, observation time, continuity of research object, subjective factors of the evaluators, quality control, etc., with the total score is 11, among which 0-3 is considered as low quality, 4-7 is considered as medium quality, and 8-11 is considered as high quality.

Strategy of data synthesis: Meta-analysis of case-control literature data was performed using Review Manager5.3 software, and results were described by odds ratio (OR) and 95% confidence interval (CI), and forest plot were drawn. Meta-analysis of cross-sectional studies was performed using Stata 14.0 software, and the results were described by effect size (ES) and its 95% CI, and forest plot were drawn. Heterogeneity was tested by I². If the heterogeneity was large (I²≥50%), the random-effects model was used. If the heterogeneity was small (I²<50%), the

fixed-effects model was used. P < 0.05 was considered statistically significant.

Subgroup analysis: Subgroup analysis was performed by region (South China, East China, and North China), gender (male, female), and age stage (≤50, 50-60, and > 60). Subgroup analysis was performed by region, sex and age.

Sensitivity analysis: Stata software conducts sensitivity analysis, and reflects the sensitivity of the article by deleting the change of effect size after a certain article

Language: No restriction.

Country(ies) involved: China.

Keywords: pre-diabetes mellitus; Traditional Chinese medicine constitution; Meta-analysis.

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