INPLASY PROTOCOL

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None declared.

Effect of exercise intervention based on family management or self- management on glycemic control in Patients with type 2 diabetes mellitus: A protocol for systematic review and meta-analysis

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Review question / Objective: **We aimed to to evaluate the effectiveness of exercise intervention based on family management or self- management on glycemic control in patients with type 2 diabetes.**
Condition being studied: **Type 2 diabetes is a common disease of the endocrine metabolic system and a metabolic disorder resulting from decreased insulin sensitivity of target tissues such as liver, muscle, and adipose tissue.Current conventional treatments include exercise interventions, dietary interventions and pharmacological interventions. Mounting evidence indicates that exercise is beneficial for the treatment of type 2 diabetes mellitus. Compared with pharmacological interventions, exercise interventions are not only less costly but also less harmful to the human body. If the patients can exercise independently or with the family members, it can improve compliance in patients with type 2 diabetes.This can not only allow patients to exercise for a long time, but also improve the cost effectiveness and practicality of condition management.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 January 2023 and was last updated on 15 January 2023 (registration number INPLASY202310046).

INTRODUCTION

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METHODS

Participant or population: All participants must be humans (≥18 years old) diagnosed with T2DM, medically defifined by a diagnosis of fasting blood glucose level of ≥7.0 mmol/L (≥126 mg/dL), a 2-h plasma glucose of ≥11.1 mmol/L (≥200 mg/dL), or a hemoglobin A1c (HbA1c) of ≥6.5%.

Intervention: Exercise intervention based on family management or self-management.

Comparator: Control or comparison group (routine treatment or Non-exercise intervention).

Study designs to be included: Only randomized controlled clinical trials (RCTs) related to the effects of exercise intervention based on family management or self- management for treating Type 2 diabetes will be included in this review. Trials published in the form of dissertations will be also selected as eligible studies.

Eligibility criteria: ①More than 50 % of exercise interventions are conducted in the community and will include a specific exercise intervention program (FITT) ②Management: self-management: exercise at home on their own or any autonomous forms of exercise after the practitioner may provide a prescription or plan of exercise initially to the patient; family management: exercise accompanied by family members.

Information sources: Relevant studies will be searched from the databases of PubMed, EMBASE, Web of Science,The Cochrane Library,China National Knowledge Infrastructure, Weipu Database for Chinese Technical Periodicals and Wanfang Database.

Main outcome(s): HbA1c, recorded as percentage change, and fasting blood glucose, measured in the unit of mmol/L.

Additional outcome(s): BMI、blood pressure、triglycerides, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, 2-h plasma glucose

Quality assessment / Risk of bias analysis: We will use the Cochrane Collaboration's tool which is recommended by the Cochrane Reviewer's Handbook to assess risk of bias for quality assessment of the included studies. The studies will be graded based on:(i) random sequence generation;(ii) allocation concealment; (iii)blinding of participants, staff, and outcome assessors; (iv) completeness of outcome data;(v) selective outcome reporting;(vi)other sources of bias.The resulting evaluation was classifified into 3 grades: low, unclear, and high risk of bias.

Strategy of data synthesis: Comparisons will be made between exercise intervention group and control or comparison group.The data of the study included may be divided into two cases, depending on whether the data are suitable for meta-analysis. If the meta- analysis is not be performed because of heterogeneity, interventions, comparisons, outcomes etc., we will make forms for a qualitative description. If the data is suitable for meta-analysis, we will perform the meta-analysis using the software Rev Man 5.4(Review Manager) and Stata 15.0. Since all the experimental data included in this study are continuous variables, we will present the results as weighted mean difference (WMD) or standardized mean difference (SMD) . Overall effect was tested using a Z-test with 95% confidence interval (CI).Levels of heterogeneity will be evaluated using I^2

statistics and Cochran's Q test. If there is statistical heterogeneity ($I^2 \geq 50\%$ or $P \leq 0.10$), the source of the heterogeneity should be further analyzed.If there is no statistical heterogeneity among the results ($I^2 < 50\%$ and $P > 0.10$), the fixed effects model is employed for meta-analysis. If there is a statistic heterogeneity, the source of the heterogeneity should be further analyzed. If there is obvious clinical heterogeneity, the subgroup or sensitivity analysis, or only descriptive analysis can be performed.When the number of selected studies approaches ten or more, publication bias will be examined by using a funnel plot and Egger regression.

Subgroup analysis: If there is a significant heterogeneity in the included trials, we will conduct subgroup analysis based on the type of exercise and duration of interventions.

Sensitivity analysis: To verify the reliability of our meta-analysis results, we will conduct a sensitivity analysis by removing each study one by one to assess the consistency and quality of results.

Country(ies) involved: China.

Keywords: Type 2 diabetes mellitus; Exercise intervention; family management or self- management; Blood glucose.

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