

INPLASY PROTOCOL

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None declared.

Comparison of the efficacy between low-carbohydrate diets and low-fat diets in type 2 diabetes mellitus: A protocol for systematic review and meta-analysis

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Review question / Objective: This systematic review and meta-analysis was performed to compare the efficacy of low-carbohydrate diets (LCDs) with low-fat diets (LFDs) in the management of type 2 diabetes mellitus (T2DM).

Condition being studied: Type 2 diabetes mellitus.

Eligibility criteria: The literature selection will be performed according to the abovementioned eligibility criteria by two reviewers independently, and any dispute will be solved by the discussion. The inclusion criteria are as follows: (1) Participants: Patients with T2DM older than 18 years; (2) Intervention: LCDs for T2DM patients; (3) Comparison: LFDs for T2DM patients; (4) Outcomes: Glycated haemoglobin (HbA1c, %) and weight loss; (5) Study design: retrospective or prospective studies. The exclusion criteria include type 1 DM, animal or cell experiments, studies with incomplete data, duplicated patients or literatures, case reports, reviews, surgical techniques, and editorials.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 February 2022 and was last updated on 25 February 2022 (registration number INPLASY202220074).

INTRODUCTION

Review question / Objective: This systematic review and meta-analysis was performed to compare the efficacy of low-carbohydrate diets (LCDs) with low-fat diets (LFDs) in the management of type 2 diabetes mellitus (T2DM).

Condition being studied: Type 2 diabetes mellitus.

METHODS

Participant or population: Patients with type 2 diabetes mellitus.

Intervention: Patients received the low-carbohydrate diets.

Comparator: Patients received the low-fat diets.

Study designs to be included: Retrospective or prospective studies.

Eligibility criteria: The literature selection will be performed according to the above mentioned eligibility criteria by two reviewers independently, and any dispute will be solved by the discussion. The inclusion criteria are as follows: (1) **Participants:** Patients with T2DM older than 18 years; (2) **Intervention:** LCDs for T2DM patients; (3) **Comparison:** LFDs for T2DM patients; (4) **Outcomes:** Glycated haemoglobin (HbA1c, %) and weight loss; (5) **Study design:** retrospective or prospective studies. The exclusion criteria include type 1 DM, animal or cell experiments, studies with incomplete data, duplicated patients or literatures, case reports, reviews, surgical techniques, and editorials.

Information sources: The PubMed, Cochrane Library, Embase, and Web of Science will be comprehensively searched to retrieve the relevant studies using the combination of following key words: “diabetes mellitus”, “low-carbohydrate diets”, and “low-fat diets”.

Main outcome(s): Glycated haemoglobin (HbA1c, %) and weight loss.

Quality assessment / Risk of bias analysis: (1) For the randomized controlled trial (RCT), the “risk of bias assessment” tool in Cochrane System Assessment Manual 5.0 was applied to assess the risk of bias. The Cochrane System Assessment Manual 5.0 contains seven main parts: stochastic method, allocation concealment; adopt blinding to volunteers and researchers; adopt blinding to evaluator; the completeness of research data; selective reporting study outcomes, and other bias. And the RCT study will be divided into three classes according to the Cochrane System Assessment Manual 5.0: high,

unclear, or low risk of bias. (2) For non-RCT study, the quality of included study was evaluated by Newcastle-Ottawa Scale, and the Newcastle-Ottawa Scale with value ≥ 7 is considered as high quality. There will be two researchers independently evaluating the quality of included studies with a group discussion for any discrepancy.

Strategy of data synthesis: The changes of glycated haemoglobin (HbA1c, %) and body weight loss from baseline to the last follow-up between LCD group and LFDs group were compared using the mean difference (MD) with 95% confidence intervals (CIs) according to the Z-test.

Subgroup analysis: To comprehensively compare the changes of glycated haemoglobin (HbA1c, %) and body weight loss between two groups and reduce the potential obvious heterogeneity, subgroup analyses will be performed according to different grouping standards, such as study region, study design, and quality of included studies.

Sensitivity analysis: The sensitivity analysis was conducted to reflect the effect of an individual study on the pooled results.

Country(ies) involved: China.

Keywords: type 2 diabetes mellitus, low-carbohydrate diets, low-fat diets.

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