INPLASY PROTOCOL

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None declared.

The effects of Mediterranean-style diet on glycemic control, cardiovascular risk factors and weight loss in patients with type 2 diabetes: a meta-analysis of randomized controlled trials

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Review question / Objective: **Mediterranean-style diet(MSD) has proven to be beneficial for helping to improve glycemic control, reducing the associated cardiovascular risk and weight loss, but the results are inconsistent. In this present study to explore the impact of the MSD on glycemic control, cardiovascular risk factors weight loss in patients with type 2 diabetes(T2D) by a meta-analysis of randomized controlled trials(RCTs).**
Eligibility criteria: **(1) Parallel or cross-over RCT,(2) Participants aged ≥ 18 years, (3) Samples comprised with already diagnosed T2D, (4) The period of MSD intervention at least lasted for 6 month, (5) Results reported to evaluate the effect of the MSD including HbA1c at least, (6) Studies published in English.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 June 2021 and was last updated on 25 June 2021 (registration number INPLASY202160096).

INTRODUCTION

Review question / Objective: **Mediterranean-style diet(MSD) has proven to be beneficial for helping to improve glycemic control, reducing the associated cardiovascular risk and weight loss, but the results are inconsistent. In this present study to explore the impact of the MSD on glycemic control, cardiovascular risk factors weight loss in patients with type 2 diabetes(T2D) by a meta-analysis of randomized controlled trials(RCTs).**

Condition being studied: **The pandemic of type 2 diabetes (T2DM) has reached an**

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epidemic level and shows no signs of abatement, with 592 million cases projected by the year 2035. The main characteristics of T2DM are that raise of blood glucose, insulin resistance, and low insulin sensitivity. It has been widely accepted that obesity is the most important risk actor for T2DM; being overweight or obese account for about 90% of all T2DM cases. Moreover, most patients with T2DM display dyslipidemia, hypertension, and hyperinsulinemia, which are associated with metabolic syndrome, and have an increased risk for premature cardiovascular disease. In view of its severity, there is a need for new therapeutic approaches to manage T2D. It is well established that life style interventions, including dietary changes, have a vital role in preventing the progression of impaired fasting glucose or impaired glucose tolerance to T2D. However, there is limite devidence on appropriate dietary strategy to manage hyperglycemia in T2D patients. The Mediterranean diet has been widely reported to be the optimal diet for contributing to a beneficial health status.

METHODS

Participant or population: Patients with type 2 diabetes. we do not apply any restrictions in terms of age, gender and ethnicity.

Intervention: Mediterranean-style diet.

Comparator: High-carbohydrate diet, 2003 American Diabetes Association(ADA) diet, Low-fat diet and usual dietary.

Study designs to be included: RCTs on the effects of Mediterranean-style diet on glycemic control, cardiovascular risk factors and weight loss in patients with type 2 diabetes will be included in this study.

Eligibility criteria: (1) Parallel or cross-over RCT,(2) Participants aged ≥ 18 years, (3) Samples comprised with already diagnosed T2D, (4) The period of MSD intervention at least lasted for 6 month, (5) Results reported to evaluate the effect of the MSD including HbA1c at least, (6) Studies published in English.

Information sources: We have searched candidate studies to evaluate the effects of Mediterranean-style diet on glycemic control, cardiovascular risk factors and weight loss in patients with type 2 diabetes through PubMed, Embase and the Cochrane Library until April 2021.

Main outcome(s): The main results were classified into three categories:(1) glycemic control including HbA1c and fasting plasma glucose(FPG), (2) weight control including body mass index(BMI) and waist circumference(WC), (3) cardiovascular risk factors including high-density lipoprotein cholesterol(HDL), low-density lipoprotein cholesterol(LDL), systolic blood pressure(SBP) and diastolic blood pressure(DBP).

Quality assessment / Risk of bias analysis: Study quality was assessed by Cochrane Collaboration's tool, which included six categories were sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcomes reporting and other risk of bias. The above six risk of bias domains were classified into three levels as a low risk of bias, an uncertain risk if bias and a high risk of bias. The studies quality assessment was done independently by two researchers, any disagreement between the two researchers were solved by the third researcher or group discussion.

Strategy of data synthesis: Data analysis were carried out using Review Manager 5.3 software. Standardised mean differences between MSD and control diet with 95% confidence intervals(CIs) were calculated for continuous outcomes. Missing standard deviations were computed by standard errors, 95% CIs and P-values for some studies.

Subgroup analysis: If the heterogeneity source can not be found after sensitivity analysis, we will perform further subgroup analysis.

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Sensitivity analysis: We will use the leave-one-out method for sensitivity analysis to judge the stability of outcome indicators.

Country(ies) involved: China.

Keywords: Mediterranean Diet, Type 2 Diabetes, Meta-analysis.

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