INPLASY PROTOCOL

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Review Stage at time of this submission: Piloting of the study selection process.

Conflicts of interest:
None declared.

Effectiveness of transtheoretical model-based intervention on blood glucose in Adults with Type 2 Diabetes Mellitus : a systematic review and meta-analysis

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Review question / Objective: This study aimed to systematically identify, critically evaluate, and synthesize available evidence regarding the effectiveness of transtheoretical model (TTM) interventions to control blood glucose in Type 2 Diabetes Mellitus (T2DM). The review questions of this study are: Is the application of TTM effective to control blood glucose in adult with T2DM? Is there any difference between Chinese and English Studies on TTM effective to control blood glucose in adult with T2DM? What is the appropriate intervention time for TTM effective to control blood glucose in adult with T2DM? Is there any difference between intervention method and scope on TTM effective to control blood glucose in adult with T2DM? Which stage of T2DM is the focus?

Eligibility criteria: (a) studies containing participants of T2DM patients with uncontrolled blood glucose ($\geq$18 years old); (b) intervention studies using the transtheoretical model and (c) studies containing the primary outcome(Hemoglobin A1C or Fasting blood glucose or 2 hours postprandial blood glucose).

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 February 2023 and was last updated on 28 February 2023 (registration number INPLASY202320123).

INTRODUCTION

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Condition being studied: TTM is the most commonly used health behavior model, it has been successfully used in many studies on health behavior change of diabetes. There are many researchers have conducted TTM-based intervention studies on the self-management of patients with diabetes through diet control, physical exercise, mobile medical treatment and other measures, and it has been confirmed TTM-based intervention can improve the self-efficacy of diabetic patients, stimulate their initiative and potential, prevent and reduce complications, and reduce the disease burden of family and society. However, the effect of blood glucose control is still unclear, although it is the most important indicator of T2DM. Therefore, it is important to comprehensively summarize the effect of TTM-based intervention on blood glucose control in adults with T2DM.

METHODS

Search strategy: The search term combinations we used were [T2DM OR Type 2 diabetes mellitus OR DM2 OR Type 2 diabetes] AND [Transtheoretical Model OR TTM OR stages of change model OR stage of change OR Precontemplation stage OR Contemplation stage OR Preparation stage OR Action stage OR Maintenance stage OR transtheoretical model of change] AND [blood glucose OR glycemic OR glucose OR blood sugar OR Hemoglobin A1C OR HbA1c]. The databases used to search for the published articles were PubMed, EMBASE, Scopus, WANFANG,WEIPU.

Participant or population: T2DM patients with uncontrolled blood glucose (≥18 years old).

Intervention: Intervention using the transtheoretical model.

Comparator: Usual care or control group. Usual care at least a control group or a non-based TTM or intervention group.

Study designs to be included: Only randomized controlled trials(RCTs) were included.

Eligibility criteria: (a) studies containing participants of T2DM patients with uncontrolled blood glucose (≥18 years old); (b) intervention studies using the transtheoretical model and (c) studies containing the primary outcome (Hemoglobin A1C or Fasting blood glucose or 2 hours postprandial blood glucose)

Information sources: Database: PubMed, EMBASE, Scopus, WANFANG, WEIPU.

Main outcome(s): Hemoglobin A1C or Fasting blood glucose or 2 hours postprandial blood glucose.

Additional outcome(s): BMI、Quality of life、Diabetes Self-Care Scale（2-DSCS）、Diabetes self-efficacy 、physical activity.

Quality assessment / Risk of bias analysis: Cochrane Risk of Bias Assessment Tool.

Strategy of data synthesis: We summarized study characteristics, including publication year, country, study design, Objective, participants' characteristics, application of the transtheoretical model, Primary Outcome, and Secondary Outcome.For the meta-analysis, we entered the data into the Review Manager (Revman) version 5.3 program based on each study design and outcome measurement (number of participants, mean, standard deviation, and p-value). The outcomes of the study were addresses using standardized mean difference (SMD) and 95% CI, as well as the p-values of SMDs. To reduce the effect of statistical heterogeneity on the evaluation, we used a random-effects model. Heterogeneity among studies was

assessed using I2 to determine the heterogeneity of studies.

Subgroup analysis: Subgroup analysis according to different Publisher country (China, others) and period of intervention (6 months, 12months), Intervention method (traditional consultation, SMS consultation, and Web consultation), Intervention scope(diet, exercise, medication, monitoring, others), and Stages of change (precontemplation stage, contemplation stage, preparation stage, action stage, maintenance stage).

Sensitivity analysis: This study used a funnel plot to visualize publication bias and asymmetry.

Country(ies) involved: China.

Keywords: Transtheoretical model, Type 2 Diabetes Mellitus, blood glucose control.

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