INPLASY PROTOCOL

Corresponding author:
Xiaoqiong Luo

huhc1213@163.com

Author Affiliation:
Chongqing Traditional Chinese Medicine Hospital

Review Stage at time of this submission: Preliminary searches.

Conflicts of interest:
All authors involved in this work have no conflicts of interest.

Evaluation of walking exercise on glycemic control in patients with type 2 diabetes mellitus: a protocol for systematic review and meta analysis of randomized cross-over controlled trials

Hu, H[1]; Lei, Y[2]; Luo, X[3]; Yin, L[4].

Review question / Objective: 1. Does walking exercise decrease blood glucose in patients with type 2 diabetes mellitus? 2. Does walking exercise improve insulin resistance in patients with type 2 diabetes mellitus? 3. How long does it take to walk to achieve better intervention effects? 4. Which one has better hypoglycemic effect between continuous walking and interval walking? 5. Whether walking intensity has impact on glycaemic control?

Condition being studied: Clinical trials indicated that walking exercise could improve glycemic control in patients with type 2 diabetes mellitus, but it is difficult to draw definitive and reliable conclusions due to the small sample size and possible exaggerated efficacy of various individual clinical trials. Therefore, we will conduct systematic review and meta-analysis to assess the current evidence for the efficacy of walking on glycemic control.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 September 2020 and was last updated on 10 September 2020 (registration number INPLASY202090046).

INTRODUCTION

Review question / Objective: 1. Does walking exercise decrease blood glucose in patients with type 2 diabetes mellitus? 2. Does walking exercise improve insulin resistance in patients with type 2 diabetes mellitus? 3. How long does it take to walk to achieve better intervention effects? 4. Which one has better hypoglycemic effect

between continuous walking and interval walking? 5. Whether walking intensity has impact on glycaemic control?

Condition being studied: Clinical trials indicated that walking exercise could improve glycemic control in patients with type 2 diabetes mellitus, but it is difficult to draw definitive and reliable conclusions due to the small sample size and possible exaggerated efficacy of various individual clinical trials. Therefore, we will conduct systematic review and meta-analysis to assess the current evidence for the efficacy of walking on glycemic control.

METHODS

Search strategy: We will search the following electronic databases: PubMed, Embase, Cochrane Library and Web of Science. The date will be restricted from January 2000 to July 2020. English language will be searched only.

Participant or population: Patients with type 2 diabetes mellitus.

Intervention: Walking exercise.

Comparator: Any type of treatment or no treatment.

Study designs to be included: Randomized cross-over controlled trials

Eligibility criteria: Inclusion criteria (1) Participants: patients with type 2 diabetes mellitus; (2) Intervention: walking with all frequency, time and intensity; (3) Control: any type of treatment or no treatment; (4) Outcomes: mean glucose levels, HbA1c and mean amplitude of glycemic excursions are the primary outcomes, glucose infusion rate (GIR), insulin, C-peptide, maximum glucose levels, minimum glucose levels are the secondary outcomes; (5) Study design: randomized cross-over controlled trials; (6) Language: English. Exclusion criteria (1) Participants: adolescents with T2DM (under 18 years of age); (2) Study design: those studies that were not randomized cross-over controlled trials will not be included in the study; (3)

Pilot studies; (4) Reviews; (5) Duplicate publication; (6) Studies without full-text.

Information sources: The PubMed, EMBASE, Web of Science and Cochrane Library databases will be systematically searched for this review with language restriction to English. Other restrictions will be imposed on publication time from January 2000 to July 2020. Search methods of MeSH terms with free words will be adopted in English databases. The related terms are as follows: Participants (Diabetes Mellitus, Type 2 [MeSH], 'Diabetes Mellitus, Stable','Stable Diabetes Mellitus', 'Diabetes Mellitus, Type II', 'Type 2 Diabetes Mellitus', 'Diabetes Mellitus, Type 2', 'Type 2 Diabetes', 'Diabetes, Type 2','Type II diabetes mellitus', 'Type II diabetes', 'diabetes, Type II'. Intervention (walking [MeSH], walking, ambulation, walking exercise, walking training). In addition, some unpublished studies and other relevant literature will be identified through ClinicalTrials.gov registry and Google scholar.

Main outcome(s): Mean glucose levels, HbAlc and mean amplitude of glycemic excursions are the primary outcomes.

Additional outcome(s): Glucose infusion rate (GIR), insulin, C-peptide, maximum glucose levels, minimum glucose levels are the secondary outcomes.

Quality assessment / Risk of bias analysis: The risk of bias of eligible studies will be assessed by using the Cochrane risk-of-bias assessment tool . According to this tool, the risk of bias of study is assessed from 7 items: random sequence generation and allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias) and other bias.

Strategy of data synthesis: We will conduct quantitative analysis if the outcome indicators include more than two studies, otherwise use narrative analysis. Mean

glucose levels, glycosylated hemoglobin, mean amplitude of glycaemic excursions, glucose infusion rate (GIR), insulin, C-peptide, maximum glucose levels and minimum glucose levels will be synthesised.These outcome indicators are continuous variables, so standardized mean difference (SMD) will be used to express the effect sizes for these continuous outcomes. SMD for individual studies will be combined using a random effects meta-analysis.

Subgroup analysis: If there is substantial heterogeneity between studies, then subgroup analysis will be conducted to investigate the sources of heterogeneity. The grouping factors for subgroup analysis are as follows: walking frequency, walking intensity, walking time and BMI.

Sensibility analysis: We will omit each study that is included in meta-analysis one by one if there are sufficient studies. If there is study of large sample size, we will convert the random effects model to fixed effects model to compare the changes in the pooled results.

Country(ies) involved: China.

Keywords: walking, type 2 diabetes mellitus, glycemic control, meta-analysis, protocol.

Contributions of each author:
Author 1 - Hengchang Hu - Data curation, formal analysis, methodology, software and writing-original draft will be conducted by Author 1.
Author 2 - Yuanhong Lei - Data curation and formal analysis will be conducted by Author 2.
Author 3 - Xiaoqiong Luo - Conceptualization, data curation, project administration,resources and supervision will be conducted by Author 3.
Author 4 - Liping Yin - Methodology, writing-Review and editing will be conducted by Author 4.