INPLASY PROTOCOL

To cite: Sun et al. Efficacy and safety evaluation of acupuncture in the treatment of impaired glucose regulation:a protocol for systematic review and meta-analysis. Inplasy protocol 202170058. doi: 10.37766/inplasy2021.7.0058

Received: 19 July 2021

Published: 19 July 2021

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Support: **SF(NO.20200403124).**

Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
None declared.

Efficacy and safety evaluation of acupuncture in the treatment of impaired glucose regulation: a protocol for systematic review and meta-analysis

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Review question / Objective: **To prove the efficacy and safety of acupuncture in the treatment of impaired glucose regulation.**
Condition being studied: **Acupuncture in the treatment of impaired glucose regulation. We will include randomized controlled trials (RCTs) related to acupuncture for impaired glucose regulation. There are no restrictions on the language or status of publication. Patients of all ages, genders and ethnicities with impaired glucose regulation will be included.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 July 2021 and was last updated on 19 July 2021 (registration number INPLASY202170058).

INTRODUCTION

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of all ages, genders and ethnicities with impaired glucose regulation will be included.

METHODS

Search strategy: We will search 9 electronic databases of PubMed, EMBASE, Cochrane Library, Web of Science(WOS), China National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM), Chinese Scientifific and Journal Database (VIP) and Wan Fang database (Wanfang) to identify literature of RCTs of A&M for impaired sugar regulation. Besides, we will also search Chinese Clinical Trial Registry (ChiCTR) and ClinicalTrials.gov (www.ClinicalTrials.gov/) for in-progress trials with unpublished data. Table 1 shows PubMed search strategy.

Participant or population: Patients diagnosed with impaired glucose regulation included impaired fasting glucose, impaired glucose tolerance, and impaired fasting glucose combined with impaired glucose tolerance. Impair of fasting blood glucose: fasting venous plasma glucose ≥5.6 mmol · L-1 (100 mg · DL-1) and <7.0 mmol · L-1 (126 mg · DL-1); Intravenous plasma glucose level was less than 7.8mmol · L-1(140mg · DL-1) 2 h after loading. Impaired glucose tolerance: Intravenous plasma glucose ≥7.8mmol · L-1(140mg · DL-1) and <11.1 mmol · L-1(200 mg · DL-1) at 2h after load, and fasting venous plasma glucose <7.0mmol · L-1(126mg · DL-1).

Intervention: The treatment plan of the experimental group was limited to acupuncture treatment, and there was no restriction on the type or method of acupuncture.

Comparator: The control group did not receive any acupuncture treatment (western medicine, Chinese medicine, placebo or conventional treatment).

Study designs to be included: RCT.

Eligibility criteria: Only include randomized controlled trials(RCT) published or registered before July 1, 2021, review articles, case reports and other studies that do not meet the requirements will be excluded.

Information sources: Chinese and English.We will search 9 electronic databases of PubMed, EMBASE, Cochrane Library, Web of Science(WOS), China National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM), Chinese Scientifific and Journal Database (VIP) and Wan Fang database (Wanfang) to identify literature of RCTs of acupuncture for impaired sugar regulation. Besides, we will also search Chinese Clinical Trial Registry (ChiCTR) and ClinicalTrials.gov (www.ClinicalTrials.gov/) for in-progress trials with unpublished data. We will select all eligible studies published on or before July 1,2021.

Main outcome(s): The primary outcome measures were diagnostic criteria, including: fasting venous plasma glucose level and 2h post-load venous plasma glucose level.

Additional outcome(s): Secondary outcome measure: TCM syndrome scale score.Safety refers to the incidence of adverse events (bleeding, pain, hematoma, syncope, etc.).

Data management: Two reviewers will conduct studies selecting. First, they will eliminate duplicate articles with EndNote software (V. X9.0), they will screen literature with inclusion and exclusion criteria independently. Afterward, through reading titles and abstracts, literature that is obviously not applicable will be deleted. Finally, included articles will be chosen by screening the full articles. All screening procedures will be undertaken by two researchers independently. Disagreements of decision making will be solved by referring to the third reviewer.

Quality assessment / Risk of bias analysis: Two independent reviewers will assess the risk of bias with Cochrane Risk of Bias Tool

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according to the Cochrane Handbook 5.1.0 for Systematic Reviews of Interventions. The 2 reviewers will assess 7 items, which consist of the risk of bias of sequence generation, allocation concealment, blinding of participants personnel and outcome assessment, incomplete outcome data, selective outcome reporting, and other bias. If there is disagreement during the assessing process, two reviewers will discuss or consult the third reviewer for a decision. Three evaluation grades are low, unclear, and high risk of bias.Grading of recommendations assessment, development, and evaluation reliability study (GRADE) will be implemented to assess the quality of evidence. There are 4 levels of results: very low, low, moderate, and high.

Strategy of data synthesis: We will take advantage of RevMan software (version 5.3.5) for Statistical analyses performing. Only if there is no or mild significant heterogeneity (I2.1), we will apply the fixed-effect model, or the random-effects model will be selected.

Subgroup analysis: If there exists potential heterogeneity, we will perform subgroup analysis based on methods of treatment, gender, age, or other items.

Sensitivity analysis: Robustness of the results will be assessed by sensitivity analysis performance which will focus on the processing method of missing data.

Country(ies) involved: China.

Keywords: acupunture, impaired of glucose regulation, protocol, systematic review.

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