INPLASY PROTOCOL

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Conflicts of interest:
None.

Effects of gut microbiome-targeted therapies on cardiometabolic outcomes in children and adolescents: a protocol for systematic review and meta-analysis

Yan, L[1]; Wang, M[2]; Chen, J[3]; Zhao, X[4]; Wang, H[5].

Review question / Objective: **Is there any beneficial effect of gut microbiome-targeted therapies on cardiometabolic outcomes in children and adolescents?**
Condition being studied: **Children and adolescents who are not undernourished.**
Information sources: **PubMed, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL), and Web of Science will be searched. There will be no limitation for date of publication and language. We will contact the authors of selected articles to obtain missing data and clarify unclear data.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 June 2020 and was last updated on 14 June 2020 (registration number INPLASY202060050).

INTRODUCTION

Review question / Objective: **Is there any beneficial effect of gut microbiome-targeted therapies on cardiometabolic outcomes in children and adolescents?**

Condition being studied: **children and adolescents who are not undernourished.**

METHODS

Participant or population: **Participants were 0 to ≤18 years of age at baseline. Studies**

were excluded if they included malnourished participants.

Intervention: Probiotics or synbiotics at any dose, duration, and route of administration, given separately or in combination.

Comparator: No intervention, placebo, or other interventions.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: P: Participants were 0 to ≤18 years of age at baseline. Studies were excluded if they included malnourished participants. I: Probiotics or synbiotics at any dose, duration, and route of administration, given separately or in combination. C: No intervention, placebo, or other interventions. O: Relevant outcomes; S: RCT.

Information sources: PubMed, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL), and Web of Science will be searched. There will be no limitation for date of publication and language. We will contact the authors of selected articles to obtain missing data and clarify unclear data.

Main outcome(s): Total cholesterol, HDL-C, LDL-C, triglyceride, systolic blood pressure (SBP), diastolic blood pressure (DBP), fasting blood glucose (FBG), glycated hemoglobin (HbA1c), insulin, homeostatic model assessment of insulin resistance (HOMA-IR).

Quality assessment / Risk of bias analysis: Two authors will independently evaluate the quality of selected studies using the Cochrane Collaboration's tool. The Cochrane Collaboration's tool includes six domains as follows: 1) random sequence generation; 2) allocation concealment; 3) blinding of participants and personnel; 4) blinding of outcome assessment; 5) incomplete outcome data; and 6) selective reporting. Any disagreements between two authors during the quality assessment process will be discussed with a third author.

Strategy of data synthesis: We plan to conduct the meta-analysis by using the Stata 14.0 (Stata Corp, College Station, TX) statistical software and RevMan V.5.3 software (Nordic Cochran Centre, Copenhagen, Denmark). Continuous data will be expressed using standardized mean difference or mean difference and 95% confidence intervals. Cochrane Q-test and I^2 statistics will be used to assess the inter-study heterogeneity. If I^2 ≤50%, a fixed effect model will be used to combined results of included studies. A random effect model will be used to calculate the outcome when I^2 >50%.

Subgroup analysis: When there is significant heterogeneity between studies, we will perform subgroup analysis based on types of gut microbiome-targeted therapies, intervention duration, and target population.

Sensibility analysis: We will perform sensitivity analysis to test the stability of each outcome result by removing studies with insufficient data and high risk of bias.

Country(ies) involved: China.

Keywords: Adolescent; Cardiovascular risk factors; Child; Meta-analysis; Probiotic; Synbiotic.

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