INPLASY

Effects of Bifidobacterium on patients with irritable bowel syndrome: a systematic review and meta-analysis of randomized clinical trials

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 September 2023 and was last updated on 28 September 2023.

INTRODUCTION

Review question / Objective To investigate the therapeutic impact of Bifidobacterium on patients with irritable bowel syndrome.

Condition being studied Irritable Bowel Syndrome (IBS) is a common disorder of bowel function characterized by symptoms such as abdominal pain, bloating, diarrhoea or constipation. The specific cause of IBS is not clarified, but it may be related to gut hypersensitivity, motor dysfunction, food intolerance, mental factors, and gut microbiota disorders.

METHODS

Participant or population Patients with IBS defined by Rome criteria.

Intervention Any species, strains, treatment duration, or dose of Bifidobacterium.

Comparator Placebo with no probiotic component.

Study designs to be included Randomized controlled trials, both crossover and parallel studies were eligible.

Eligibility criteria Inclusion criteriaDouble-blind, randomized, placebo-controlled trials that met the following criteria were eligible for further analysis.1.The efficacy of Bifidobacterium was compared with placebo in patients with IBS.2.Patients included in all RCTs had a well-established diagnosis of IBS.Exclusion criteria1.Patients in the intervention group received additional treatments apart from Bifidobacterium.2.The “response rate” of active treatment and placebo could not be calculated according to the data provided in the studies. 3.Participants with other bowel diseases, such as celiac disease, inflammatory bowel disease and lactose intolerance.4.Studies that not published in

full text.5.Papers published in a language other than English.

Information sources An electronic literature search was performed on Embase, PubMed, Web of Science, the Cochrane Library, and Ovid MEDLINE by two independent researchers.

Main outcome(s) Primary Outcome: The response rate of patients exhibiting clinical symptom improvement of IBS post-treatment. The "response rate" denotes the proportion of patients who experienced notable amelioration based on any IBS rating system post-treatment. Definitions may vary across studies. For instance, an improvement might be identified as participants experiencing a reduction of ≥50% in the IBS Symptom Severity Scale (IBS-SSS) or on pain intensity scales like the numerical rating scale. To assess the overall efficacy of Bifidobacterium for patients, we selected the response rate, indicating treatment effectiveness, as our primary metric.

Quality assessment / Risk of bias analysis Two authors evaluated the risk of bias for each included trial using the Cochrane Handbook for Systematic Reviewers, with disagreements resolved by another two investigators. Bias was assessed on five indicators: randomization process; deviations from the intended interventions; missing outcome data; measurement of the outcome; selection of the reported result. Each indicator contained three levels: low risk, unclear risk, or high risk of bias.

Strategy of data synthesis RevMan 5.4 was used for the meta-analysis. Effect size was presented as risk ratios (RRs) with 95% confidence intervals (CIs), and P values of less than 0.05 were considered to indicate statistical significance. Heterogeneity among studies was assessed using Cochran's Q-test, and the I2 index was used to quantify the amount of heterogeneity, with a value greater than 50% indicating substantial heterogeneity. A funnel plot was used to detect publication bias in trials included in the meta-analysis.

Subgroup analysis Subgroup analyses, considering factors such as bacterial species, dosage, and treatment duration, were conducted to identify potential sources of significant heterogeneity.

Sensitivity analysis For sensitivity analyses, one-by-one exclusion method was used, and meta-regression analysis to investigate whether there was a correlation between year of publication, age of patients and the results.

Country(ies) involved China.

Keywords irritable bowel syndrome, bifidobacterium, meta-analysis.

Contributions of each author
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Author 3 - Xiaoduo Liu.
Author 4 - Anni Zhou.