INPLASY PROTOCOL

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None declared.

Effects of Low-FODMAP diet on irritable bowel symptoms in patients with quiescent inflammatory bowel disease: A protocol for a systematic review and meta-analysis

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Review question / Objective: **The purpose of this study was to investigate the efficacy difference between low-FOdmap diet and normal diet in the treatment of quiescent inflammatory bowel disease, and the included research method was RCT clinical trial. Fecal calprotectin and quality of life scale were used as the main outcome indicators to compare and analyze the two diets.**

Information sources: **This study will be based on the reporting guidelines of the Protocols and Meta-Analysis of Systematic Reviews (PRISMA-P). We conducted this meta-analysis using previously published studies; no patients were involved in this study; therefore, no informed patient's consent and/or public ethical approval were required. We searched the following databases from their establishment until December 2021: PubMed, Web of Science, Embase, Cochrane Library, CNKI and Wanfang databases. No restrictions regarding publication date or language were applied. Keywords such as "Crohn's disease", "ulcerative colitis", "inflammatory bowel disease", and "FODMAPs" have been combined for search and the search strategy in PubMed is shown in Table 1.Ongoing and unpublished research in the Clinical Trials Registry Research will also be included. At the same time, we will manually search all reference lists from relevant systematic reviews for other eligible studies.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 February 2022 and was last updated on 16 February 2022 (registration number INPLASY202220060).

INTRODUCTION

Review question / Objective: **The purpose of this study was to investigate the efficacy difference between low-FOdmap diet and normal diet in the treatment of quiescent inflammatory bowel disease, and the included research method was RCT clinical trial. Fecal calprotectin and quality of life scale were used as the main outcome**

indicators to compare and analyze the two diets.

Condition being studied: The supporting institution of this study has the right to use CNKI, Cochrane and other databases to search relevant literatures. Most of the participants were front-line clinicians or data statisticians, with professional knowledge of IBD and data analysis ability.

METHODS

Participant or population: Patients with quiescent inflammatory bowel disease.

Intervention: The Low-FODMAPdiet.

Comparator: Normal diet.

Study designs to be included: Randomized controlled trial.

Eligibility criteria: Inflammatory bowel disease diagnosed according to the standards of the American Gastrointestinal Association or the European Society for Gastrointestinal Endoscopy.

Information sources: This study will be based on the reporting guidelines of the Protocols and Meta-Analysis of Systematic Reviews (PRISMA-P). We conducted this meta-analysis using previously published studies; no patients were involved in this study; therefore, no informed patient's consent and/or public ethical approval were required. We searched the following databases from their establishment until December 2021: PubMed, Web of Science, Embase, Cochrane Library, CNKI and Wanfang databases. No restrictions regarding publication date or language were applied. Keywords such as "Crohn's disease", "ulcerative colitis", "inflammatory bowel disease", and "FODMAPs" have been combined for search and the search strategy in PubMed is shown in Table 1.Ongoing and unpublished research in the Clinical Trials Registry Research will also be included. At the same time, we will manually search all reference lists from relevant systematic reviews for other eligible studies.

Main outcome(s): The primary outcome measures will include the gut symptoms, patient quality of life, disease activity.

Additional outcome(s): The secondary outcome measures will include inflammatory markers fecal calprotectin.

Quality assessment / Risk of bias analysis: Two investigators will separately assess the risk of bias of the selected RCTs by the Cochrane risk of bias assessment tool. It consists 7 items: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias.We will use Begg and Egger tests and set P<.1 as statistically significant, and we will use a funnel chart to assess publication bias.

Strategy of data synthesis: STATA software was used for registry analysis, and I squared > 50% and P < 0.1 were considered as heterogeneity, heterogeneity selection random effect combined effect size, and heterogeneity selection fixed effect combined effect size.

Subgroup analysis: A subgroup analysis will be performed for ulcerative colitis and Crohn's disease.

Sensitivity analysis: STATA software was used for sensitivity analysis, and the sensitivity of the literature was corrected by the change of effect size after deleting one of the literature.

Language: No language limits in the study.

Country(ies) involved: China.

Keywords: Inflammatory bowel disease; Ulcerative cilitis; crohn disease; Low-FODMAP diet.

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