# INPLASY PROTOCOL

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

**Conflicts of interest:**
**None.**

# A comparison of the efficacy and safety of complementary and alternative therapies for ulcerative colitis: A protocol for systematic review and meta-analysis

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**Review question / Objective:** **This review aims to systematically evaluate the efficacy and safety of complementary and alternative therapies for ulcerative colitis patients reported in randomized clinical trials (RCTs).**
**Condition being studied:** **The incidence of ulcerative colitis (UC) is increasing year by year worldwide, and it is listed as one of the refractory diseases by WHO. In addition to typical intestinal manifestations such as abdominal pain, diarrhea, mucus, pus and bloody stool, it can also accompany multi-organ and multi-system extraintestinal manifestations, seriously affecting the life and work of patients. Furthermore, UC patients with a tremendous psychological pressure on patients and affects their physical and mental health.**

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 June 2020 and was last updated on 03 June 2020 (registration number INPLASY202060015).

## INTRODUCTION

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**Condition being studied:** **The incidence of ulcerative colitis (UC) is increasing year by year worldwide, and it is listed as one of the refractory diseases by WHO. In addition to typical intestinal manifestations such as abdominal pain, diarrhea, mucus, pus and bloody stool, it can also accompany multi-organ and multi-system extraintestinal manifestations, seriously affecting the life**

and work of patients. Furthermore, UC patients with a tremendous psychological pressure on patients and affects their physical and mental health.

## METHODS

**Participant or population:** The population includes patients with UC. We do not impose restrictions on gender, race, region or other characteristics.

**Intervention:** The treatment group was treated with complementary and alternative therapies, either alone or in combination with other treatments.

**Comparator:** The control group does not use complementary and alternative therapies or drug therapy, and the treatment was commonly used clinical drugs.

**Study designs to be included:** This study includes all relevant randomized controlled trials (RCTs) of complementary and alternative therapies for UC published in Chinese or English.

**Eligibility criteria:** Only randomized controlled trials are included. Patients with other intestinal diseases, as well as those with other serious diseases will be excluded. Non-randomized controlled trial, self-control, case report, experience summary, animal experiment research, systematic review, and meta-analysis will also be excluded.

**Information sources:** PubMed, the Cochrane Controlled Trials Central Register System (CENTRAL) Cochrane Library, EMBASE, China National Knowledge Infrastructure (CNKI), Wanfang Database, VIP, and Chinese Biomedical Literature database (CBM).

**Main outcome(s):** The primary outcome measures are improvements in clinical symptoms such as mucus pus and bloody stools, and clinical effectiveness.

**Quality assessment / Risk of bias analysis:** Risk of bias in the included studies will be assessed by the the Cochrane Risk of Bias Tool according to the Cochrane Handbook 5.1.0 for Systematic Reviews of Interventions, which consists of 7 items of bias relevant to the quality of RCTs.

**Strategy of data synthesis:** Using Revman 5.3 software provided by Cochrane Collaboration Network, meta-analyses were carried out for the included researches. When $P>0.05$ , we generally determined that there is no heterogeneity among the studies, fixed-effects model is selected for analysis, otherwise random-effects model is selected. In addition, we also use I2 for quantitative analysis of heterogeneity, the statistics of efficacy index analysis use Odds Ratio (OR), continuous variables use weighted mean difference (WMD), and 95% confidence interval (CI) is given.

**Subgroup analysis:** If the included evidence is rich, we will conduct a subgroup analysis of the study.

**Sensibility analysis:** This process will be carried out by eliminating each included study. If the heterogeneity does not change after excluding each literature, we think our conclusion is stable.

**Language:** English.

**Country(ies) involved:** China.

**Keywords:** ulcerative colitis, complementary and alternative therapies; protocol; systematic review; meta-analysis.

**Contributions of each author:**
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