Feasibility of a multimodal intervention program to optimize treatment outcomes in Ulcerative Colitis. A prospective pilot study.

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Primary Objective: To assess the feasibility of a multimodal intervention program for patients UC. Secondary Objectives: To investigate the effects of a multimodal intervention program on: - An individual patient*s level, i.e. physical fitness (…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON53311

Source
ToetsingOnline

Brief title
OPTIMIZE-UC

Condition

- Gastrointestinal inflammatory conditions
- Autoimmune disorders

Synonym
Inflammatory Bowel Disease, Ulcerative Colitis

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Bristol Myers Squibb

Intervention

Keyword: Diet, Exercise, Lifestyle, Ulcerative Colitis

Outcome measures

Primary outcome

This study assesses the feasibility and optimal timing of a multimodal

intervention program.

Feasibility is assessed by:

- Accrural

- Attrition

- Adherence to the program

- Satisfaction

- Safety

Secondary outcome

To investigate the effects of a multimodal intervention program on:

o An individual patient*s level, i.e. physical fitness (estimated VO2 peak,

indirect 1 repetition measures, physical activity), nutritional status (body

weight, fat-free mass, Patient-Generated Subjective Global Assessment

(PG-SGA)), mental health (HADS), quality of life (IBDQ, SF-36, EQ-5D-5L) and

Work Productivity and Activity Impairment (questionnaire in Appendix IV).

o Therapy outcomes: e.g. number and severity of (S)AEs, corticosteroid use,

biochemical and clinical response/remission rates and patient reported outcomes.

Study description

Background summary

Despite considerable advances in the knowledge of UC, and a variation of treatment options, UC still impacts patients* ability to lead a normal life. Clearly, there is an unmet need to improve treatment outcomes. Intervention programs in preparation for surgery have shown that the amount of complications is closely related to preoperative physical fitness, nutritional status and psychological well-being. IBD patients often search for self-management strategies to manage their symptoms, however, research focussing on a multimodal intervention approach in patients with active disease is lacking. Given the potential benefits of intervention programs, limitations of current treatments in terms of improving quality of life and patients* desire for self-management options, we believe that exploring the results of a multimodal intervention program in patients with active UC, as well as UC in remission, is of high relevance.

Study objective

Primary Objective: To assess the feasibility of a multimodal intervention program for patients UC.

Secondary Objectives: To investigate the effects of a multimodal intervention program on:
- An individual patient*s level, i.e. physical fitness (estimated VO2 peak, indirect 1 repetition measures, physical activity), nutritional status (body weight, fat-free mass, Patient-Generated Subjective Global Assessment (PG-SGA)), mental health (HADS), quality of life (IBDQ, SF-36, EQ-5D-5L) and Work Productivity and Activity Impairment (questionnaire in Appendix IV).
- Therapy outcomes: e.g. number and severity of (S)AEs, corticosteroid use, biochemical and clinical response/remission rates and patient reported outcomes.

Study design

This is a feasibility study. Participants will receive standard care and follow-up, but will on top of that participate in the multimodal intervention program.

Intervention

Patients will participate in a multimodal intervention program including an exercise program, nutritional intervention and psychological support if screened at risk using a screening questionnaire.

Study burden and risks

It is very likely that patients will benefit from partaking in this program, as they will be working on their physical, mental and nutritional health. No minors and incapacitated subjects will be included. Participating in this trial will not delay standard care in any way. Exercise is not expected to cause risk to patients. The amount of tests might be perceived as a burden for patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

o Age >= 18 years old;
o Diagnosis of Ulcerative Colitis confirmed by clinical, endoscopic, and/or histological evidence prior to screening as per standard criteria;
o Written informed consent must be obtained and documented.

Exclusion criteria

o Suspicion of differential diagnosis of Crohn's Disease, indeterminate colitis, ischemic colitis, radiation colitis, diverticular disease associated with colitis, or microscopic colitis;
o Serious underlying disease other than UC that in the opinion of the investigator may interfere with the subject's ability to participate fully in the study or would compromise subject safety (such as history of malignancies, major neurological disorders, certain orthopedic impairments or any unstable, uncontrolled or severe systemic medical disorder);
o If female, the subject is pregnant or lactating (< 1 year) or intending to become pregnant;
o Immobilized patients who are not able to complete exercise intervention;
o Illiteracy (disability to read and understand Dutch).

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-05-2024
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	04-09-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT05743153
CCMO	NL83603.091.23