Crohn and Colitis Diet and Lifestyle Intervention

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26291

Source
NTR

Brief title
Crocodile

Health condition

Inflammatory Bowel Disease

Sponsors and support

Primary sponsor: Hospital Gelderse Vallei
Source(s) of monetary or material Support: Eat2Move

Intervention

Outcome measures

Primary outcome

Impact of disease on daily life as measured by the Inflammatory Bowel Disease Disability Index (IBD-DI)

Secondary outcome

Fecal calprotectin, microbiome, clinical disease activity measured by Harvey Bradshaw Index (HBI) in Crohn's Disease and the Simple Clinical Colitis Activity Index (SCCAI) in ulcerative colitis, quality of life
as measured by the Inflammatory Bowel Disease Questionnaire (IBDQ), fatigue as measured by the Inflammatory Bowel Disease Fatigue scale (IBD-F), adherence to the lifestyle (combination of dietary intake and physical activity), number of flare-ups and weight changes.

Study description

Background summary

Rationale: Several studies suggest that diet and physical activity can help to maintain remission and improve quality of life in patients with inflammatory bowel disease (IBD). Lifestyle interventions in which diet and physical activity are combined seem to be more effective than diet-only or physical activity only interventions. Such an intervention is still lacking for IBD, while many patients are willing to adjust their lifestyle as add-on therapy in IBD treatment.

Objective: The primary objective is to investigate the effect of a combined lifestyle intervention on the impact of disease on daily life. Secondary objectives will be to investigate the effect on quality of life, fatigue, clinical disease activity, fecal calprotectin and microbiome.

Study design: We propose to perform a 1-year intervention study consisting of a 3-month introduction phase, a 3-month maintenance phase and 6-months of follow-up in motivated patients. Participants will receive personal advice by a dietician and a physical therapist to improve their diet and exercise level. These advices will be supported by eHealth and an app with recipes.

Study population: The study population will consist of 30 subjects aged 18 years or older diagnosed with histologically proven Crohn's disease or ulcerative colitis (total or left-sided colitis), which should be in remission as defined by clinical disease activity scores based on HBI/SCCAI.

Intervention: Participants will receive personal advice by a dietician and a physical therapist to reduce the inflammatory potential of their diet and improve their physical activity level, in order to optimize their lifestyle.

Study objective

We hypothesize that lifestyle improvement will reduce the impact of disease on daily life, reduce fatigue and increase quality of life. It may even help to decrease the frequency, duration and severity of flares and possibly reduce the use of medication. Both subjective

and objective outcome measures will be used.

Study design

Baseline, 3 months, 6 months and 1 year

Intervention

Personalized dietary advice is based on the Dutch Healthy Eating guidelines with special emphasis on vegetables, fruits and grains. Tea, coffee, and water are the preferred drinks. Red and processed meat, soft drinks and other processed foods will be limited. Personalized physical activity advice is based on the Dutch physical activity guidelines and includes exercise and activities in daily life. If applicable smoking cessation will be advised.

Contacts

Public
Hospital Gelderse Vallei
Carlijn Lamers

0646468946
Scientific
Hospital Gelderse Vallei
Carlijn Lamers

0646468946

Eligibility criteria

Inclusion criteria

- Diagnosis of Crohn's disease or ulcerative colitis (total or left-sided colitis) made by a gastroenterologist at least two years ago and histologically proven
- 18 years of age or older
- In remission or mild disease activity that does not require immediate medication change
- At least one flare-up in the past two years

Exclusion criteria

- A total DHD-FFQ score of >140 points or a score of ≥9 points on each category

- Exercising at moderate intensity for 30 minutes or more 5 days per week or more
- Participation in another intervention study
- Not allowing to inform their general practitioner and gastroenterologist about the participation

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-02-2020
Enrollment:	30
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	06-01-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50070
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8267
CCMO	NL70073.081.19
OMON	NL-OMON50070

Study results