Crohn and Colitis Diet and Lifestyle intervention

Published: 03-12-2019
Last updated: 19-03-2025

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

Summary

ID

NL-OMON50070

Source
ToetsingOnline

Brief title
Crocodile

Condition

- Gastrointestinal inflammatory conditions

Synonym
chronic inflammation of the bowel, inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisvoorzieningen Gelderse Vallei
Source(s) of monetary or material Support: Eat2Move,Takeda

Intervention

Keyword: Crohn's disease, inflammatory bowel disease, lifestyle, ulcerative colitis

Outcome measures

Primary outcome

The main study parameter is impact of disease on daily life as measured by the IBD-DI, with lower scores representing more impact of disease.

Secondary outcome

Secondary parameters are 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

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). Currently, however, clear guidelines are lacking while many patients are willing to adjust their lifestyle as add-on therapy in IBD treatment.

Study objective

The primary objective is to assess the effect of a combined lifestyle intervention on the impact of disease on daily life as measured by the Inflammatory Bowel Disease Disability Index (IBD-DI) in patients with IBD. Secondary objectives are to assess the effect on intestinal inflammation as

measured by fecal calprotectin, changes in microbiome, clinical disease activity, quality of life, fatigue and number of flare-ups.

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.

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.

Study burden and risks

This study provides an opportunity for patients who would like to follow a combined lifestyle intervention, which is now lacking, for free. Subjects need to visit Hospital Gelderse Vallei two times for measurements and consults. Three times they are asked to collect two faecal samples. Additionally, they need to fill in online questionnaires at baseline, after 5 weeks, 3 months, 6 months and 1 year. Since the investigational treatment of this study consists of advices on commercially available food products and regular daily activities, there are no direct risks for the subjects.

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

- 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
- Between 18 years and 70 years of age
- BMI <30 kg/m2
- In remission or mild disease activity that does not require immediate medication change
- At least one flare-up in the past two years
- Signed informed consent

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
- Use of prednisone
- Participation in another intervention study
- Not allowing to inform their general practitioner and gastroenterologist about the participation

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	10-02-2020
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	03-12-2019
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	22-07-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26291
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL70073.081.19
Other	NL8267
OMON	NL-OMON26291