

Crohn and Colitis Diet and Lifestyle Intervention

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|-----------------------------|-----------------------|
| Ethische beoordeling | Positief advies |
| Status | Werving gestopt |
| Type aandoening | - |
| Onderzoekstype | Interventie onderzoek |

Samenvatting

ID

NL-OMON26291

Bron

NTR

Verkorte titel

Crocodile

Aandoening

Inflammatory Bowel Disease

Ondersteuning

Primaire sponsor: Hospital Gelderse Vallei

Overige ondersteuning: Eat2Move

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Baseline, 3 months, 6 months and 1 year

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Hospital Gelderse Vallei
Carlijn Lamers

0646468946

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

| | |
|------------------|-------------------------|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Anders |
| Toewijzing: | N.v.t. / één studie arm |
| Blinding: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

Deelname

| | |
|-------------------------|-----------------------|
| Nederland | |
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 03-02-2020 |
| Aantal proefpersonen: | 30 |
| Type: | Werkelijke startdatum |

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

| | |
|-----------------|------------------|
| Positief advies | |
| Datum: | 06-01-2020 |
| Soort: | Eerste indiening |

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50070
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten