ENERGIZE IBD - The effect of intensive physical exercise on fatigue and quality of life in patients with quiescent inflammatory bowel disease: A randomized controlled trial

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Primary Objective:To assess the effect of a 12-week moderate-vigorous intensity exercise intervention in fatigued IBD patients with quiescent disease on fatigue and health-related quality of life (HRQoL) (short term, measured at 3 months).Secondary...

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

Summary

ID

NL-OMON51459

Source
ToetsingOnline

Brief title
ENERGIZE-IBD

Condition

- Gastrointestinal inflammatory conditions

Synonym
Inflammatory bowel disease (IBD) AND Crohn's disease / ulcerative colitis

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Stichting: Maag-lever-darmstichting (MLDS)

Intervention

Keyword: Fatigue, Inflammatory Bowel disease, Physical exercise, Quality of life

Outcome measures

Primary outcome

Change in fatigue and quality of life after 12-weeks physical exercise in the intervention group compared to the control group. (short term, after 3 months)

Fatigue complaints will be measured with the inflammatory bowel disease fatigue self-assessment scale (IBD-F) and quality of life will be measured with the IBD-questionnaire (IBDQ).

Secondary outcome

• Long-term changes in fatigue and quality of life as measured after 6- and 12-months using the IBD-F and IBDQ questionnaires in the intervention group compared to the control group;

• Changes in cardiorespiratory fitness and muscular strength of patients in the intervention group after 3 months (post-intervention) assessed using CPET (including maximum power and VO2max) and strength measurements using 1-RM;

• Change in body composition in the intervention group after 3 months (post-intervention): body fat percentage measured using skinfold techniques and BMI;

• Change in work productivity and activity impairment using the work productivity cost questionnaire in the intervention group compared to the

control group;

• Disease activity measured by faecal calprotectin, exacerbation rate and step-up therapy rate in both the intervention- and control group;

• Self-reported differences in sleep quality in the intervention group compared to the control group, using the Pittsburgh Sleep Quality Index (PSQI);

• Differences in Anxiety and depression symptoms in the intervention group compared to the control group, measured using the Hospital Anxiety and Depression Scale (HADS) questionnaire;

• Economic evaluation of the intervention using a cost-utility analysis from a societal perspective including intervention costs, medical consumption costs, non-medical patient costs and productivity loss. Effectiveness of the intervention will be determined using the mean difference of quality adjusted life years (QALYs) between de intervention and control group, based on designated EQ-5D-5L questionnaire;

• Exploratory: differences in the immunological profiles, microbiome diversity and composition using 16SRNA sequencing and concentration of targeted metabolites (short-chain fatty acids and tryptophan metabolites).

Study description

Background summary

Fatigue significantly impacts the quality of life (QoL) of patients with inflammatory bowel disease (IBD) and is observed in 40% of patients with quiescent disease. Specific treatment strategies are currently lacking. Physical exercise might be an effective complementary treatment for fatigue, as our previous pilot-study has demonstrated a benificial effect on fatigue and QoL in IBD-patients. However trials with more evidence, such as a randomized

controlled trial, on the potential beneficial effect of physical exercise on IBD-related fatigue is needed. Additionally, the long-term effects and cost-effectivity of such intervention has not been determined before.

Study objective

Primary Objective:
To assess the effect of a 12-week moderate-vigorous intensity exercise intervention in fatigued IBD patients with quiescent disease on fatigue and health-related quality of life (HRQoL) (short term, measured at 3 months).

Secondary Objectives:
• To assess the effect of a 12-week moderate-vigorous intensity exercise intervention in fatigued IBD patients with quiescent disease on;
- Fatigue and HRQoL (long term, measured at 6 and 12 months);
- The physical fitness of patients including body composition, cardiorespiratory fitness and muscle strength;
- Work productivity and activity impairment;
- Disease activity;
- Self-reported sleep quality;
- Anxiety and depression symptoms;
- Furthermore, exploratory objectives include the effect of the intervention on immunological profiles, microbiome diversity and composition and gut-derived targeted metabolites (short-chain fatty acids and tryptophan metabolites)
• To assess the cost-effectiveness of a 12-week moderate-vigorous intensity exercise intervention in fatigued IBD patients

Study design

A multicentre parallel randomized controlled trial will be executed. After randomization, the study period covers a total of 12 months, including an intervention duration of 3 months and subsequently 9 months of a follow-up period to assess the long-term effects.

Intervention

A 12-week exercise program consisting of three times per week 1-hour sessions, including 30-minutes aerobic- and 30-minutes progressive resistance training at personalised intensity based on cardiopulmonary exercise test (CPET) and one-repetition maximum (1-RM). The training sessions will be performed in groups of 10 participants under supervision of a sports physiotherapist.

Study burden and risks

It is expected patients in the intervention group will benefit from the program with improvement of their fatigue complaints and quality of life. Also, those

patients will be given the opportunity to participate in a supervised exercise program free of charge. The risk of sports injuries is limited with adjustment of intensity of exercise to each individual and supervision of a sports physiotherapist. Regarding the burden for patients, they will have to fill in multiple questionnaires four times over a period of 12 months, at baseline and after the intervention blood and stool samples are needed and patients will have to perform a CPET twice. The control group will not benefit directly from this study. Completing multiple questionnaires four times over the same period of 12 months as well as blood and stool samples twice in the study period will be the presumed burden. No risks are associated with participation in the control group

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- >= 1 year diagnosis of IBD (including Crohn*s disease, ulcerative colitis and IBD-unclassified) based on a combination of clinical, endoscopic, histologic and radiologic internationally accepted criteria;
- Severe fatigue complaints >3 months as confirmed with a score of >=11 on section I of the inflammatory bowel disease fatigue self-assessment scale (IBD-F);
- Clinically quiescent IBD with a Harvey Bradshaw Index (HBI) <5 for Crohn*s disease patients or a Simple Colitis Clinical Activity Index (SCCAI) <=2 for patients with ulcerative colitis or IBD-unclassified;
- Faecal calprotectin <100 µg/g;
- Stable medication for at least 3 months before screening visit;
- Patient is able and willing to provide written informed consent;
- Patient is able/commitment to make a time investment to complete the intervention program (one hour training 3x/week during 12 weeks);
- Patient is aged between 18 and 67 years

Exclusion criteria

- Intensive sport activities more than once a week / >90 minutes in the past year.
- Past surgery within 6 months before or planned surgery 12 months after the screening visit
- Comorbidities that could be confounders for fatigue; (such as severe cardiorespitory disease, active malignancy, post-COVID or treatment for a psychiatric disorder)
-Comorbidities that prevent safe participation in the exercise program/cardiorespiratory fitness test (including cardiorespitory diseases, BMI>=35, physical disabillities that compromise exercise performances).
- Pregnant at the moment of the screening visit or planning pregnancy within 12 months after the screening.
- Participation in another medical research.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-02-2023
Enrollment:	100
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	06-10-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-10-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-09-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-07-2024
Application type:	Amendment
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
CCMO	NL81794.091.22