

The effectiveness of a sports program on fatigue and QoL in IBD patients with quiescent disease

Published: 30-11-2017

Last updated: 12-04-2024

Primary Objective: - To assess the effectiveness of a sports program on fatigue and quality of life in IBD patients with quiescent disease and chronic fatigue. Secondary Objectives: - To assess the influence of a sport program on the physical fitness...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational non invasive

Summary

ID

NL-OMON44410

Source

ToetsingOnline

Brief title

Sports and IBD

Condition

- Gastrointestinal inflammatory conditions
- Autoimmune disorders

Synonym

Inflammatory Bowel Disease/IBD/Crohn's disease and Ulcerative colitis

Research involving

Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis

Source(s) of monetary or material Support: RVE MDL

Intervention

Keyword: Crohn's disease, Fatigue, Inflammatory Bowel disease, Quality of life, Quiescent disease, Sport program, Ulcerative colitis

Outcome measures

Primary outcome

Change in fatigue complaints measured with the CIS-F checklist and in quality of life measured with the IBD-Q checklist.

Secondary outcome

Physical fitness including cardiorespiratory fitness, muscle strength and body composition.

Study description

Background summary

Ulcerative colitis (UC) and Crohn's disease (CD) are Inflammatory Bowel Diseases (IBD). IBD is a heterogeneous group of diseases regarding clinical presentation, disease course and treatment response. The incidence is increasing in the past decades and disease burden is substantial due to the chronic nature and generally young age at onset of disease. Pathogenesis is complex and multifactorial, based on interactions between genetic and environmental factors, gut microbiota and the immune system, leading to intestinal inflammation.

Besides diarrhoea, rectal blood loss, abdominal pain and weight loss, fatigue is one of the main symptoms of IBD and is frequently observed in patients in both active and quiescent disease. It is defined as a sense of continuing tiredness, with periods of sudden and overwhelming lack of energy or a feeling of exhaustion that is not relieved or fully relieved following rest or sleep and strongly influences the quality of life in these patients. 1 (Ream et al. Fatigue: a concept analysis. Int J Nurs Stud 1996) In the Netherlands, 41% patients with quiescent disease complain of severe fatigue. 2 (Minderhoud et al 2007 Crohn's disease, fatigue and Infliximab)

Treatment strategies in patients with an inflammatory bowel disease consist of a wide range of pharmacological options (e.g. steroids, thiopurines, biologicals), nutrition modification, abstinence of smoking and in a last resort surgery. Despite solution-focused psychological interventions showed to

be effective in reducing fatigue in the majority of patients, there is still a group of patients suffering from serious fatigue even in remission with a lower quality of life compared to healthy persons. 3 (Vogelaar et al, 2015 Physical fitness and physical activity in fatigued and non-fatigued inflammatory bowel disease patients) There is also a group which reported insufficient fatigue management in daily practice.

In several chronic diseases including heart failure, depression and COPD, fatigue and quality of life (QoL) improved due to physical activity as a complementary treatment. Therefore structured exercise training has been proposed as a useful adjunctive therapy for IBD patients by improving psychological health, reducing fatigue and promoting gains in physical strength. 4 (Tew et al Feasibility of HIT and MIT in adults with inactive or mildly active Crohn's disease 2017) The purpose of this study is to assess the effectiveness of a structural sports program on fatigue and QoL in IBD patients with quiescent disease and chronic fatigue.

Study objective

Primary Objective:

- To assess the effectiveness of a sports program on fatigue and quality of life in IBD patients with quiescent disease and chronic fatigue.

Secondary Objectives:

- To assess the influence of a sport program on the physical fitness including cardiorespiratory fitness, muscle strength and body composition.

Study design

The study will be a longitudinal, prospective, cohort study. It is a pilot study that will be performed at the department Sport Medical Center Papendal with patients from the department of Gastro-enterology and Hepatology of the Rijnstate Hospital. The study period covers to the utmost one year.

Study burden and risks

The benefit for the study population is that they have the opportunity to sport for free at the Sport Center Formupgrade in Arnhem. The risk for sport injuries is restricted because the sportactivities are under supervision of a physician.

Contacts

Public

Rijnstate Ziekenhuis

Wagnerlaan 55
Arnhem 6815AD
NL
Scientific
Rijnstate Ziekenhuis

Wagnerlaan 55
Arnhem 6815AD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- The diagnosis of IBD must be based on a combination of clinical, endoscopic, histologic and radiologic internationally accepted criteria in the past.
- Both patients with Crohn*s disease, Ulcerative colitis and IBD-unclassified in remission (SES-CD 0-2 and Mayo score 0).
- The faecal calprotectin must be below 50.
- Fatigue level on the Checklist Individual Strenght fatigue must be above or equal to 35 (CIS-F score *35)
- Stable medication for at least 4 weeks before the screening visit.
- Patients must be able and willing to provide written informed consent.
- Patients between the age of 25 and 60 years, both men and women.

Exclusion criteria

- IBD diagnosis within one year before the screening visit.
- Intensive sport activities more than once a week in the past year.
- Operation within 6 months before or 3 months after the screening visit
- Coexistent chronic diseases for example heart failure, COPD an malignancies.

- Pregnant at the moment of the screening visit or planning pregnancy within 3 months after the screening.
- Participation in another medical research.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 13-03-2018

Enrollment: 20

Type: Actual

Ethics review

Approved WMO

Date: 30-11-2017

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 29-03-2018

Application type: Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 27-03-2019

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	NL63369.091.17