The Effect of a Multimodal Lifestyle Intervention on Chronic Fatigue in Patients with Inflammatory Bowel Disease

Published: 24-02-2022
Last updated: 05-04-2024

Objective: to investigate if a multimodal lifestyle intervention reduces chronic fatigue and improves quality of life in patients with IBD.

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

Summary

ID

NL-OMON54056

Source
ToetsingOnline

Brief title
Multi-IBD

Condition

- Gastrointestinal inflammatory conditions

Synonym
IBD, Inflammatory Bowel Disease

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Non-profit organizatie: Maag Darm Lever

Stichting (MLDS)

Intervention

Keyword: Fatigue, IBD, Inflammatory Bowel Disease, Lifestyle

Outcome measures

Primary outcome

Primary Objective:

• How many patients, who undergo the multimodal lifestyle intervention, experience a reduction in fatigue compared with patients in the control group?

Secondary outcome

Secondary Objective(s):

• Does a multimodal lifestyle intervention improve quality of life in IBD patients with chronic fatigue?

• How significant is the reduction in fatigue in patients that undergo the multimodal lifestyle intervention?

• Does chronic fatigue change in the control group? What is the extent of the change in chronic fatigue? Does it differ from the change (and extent of it) compared with the intervention group?

• How does a multimodal lifestyle intervention:

o affect work productivity?

o remission status (assessed using both symptom scores and fecal calprotectin)?

o affect dietary quality, amount of physical exercise, sleep quality, perceived stress?

o self-efficacy, coping strategy?

o healthcare consumption?

• Is the intervention cost-effective?

Study description

Background summary

Rationale: (chronic) fatigue is more prevalent in patients with Inflammatory Bowel Disease (IBD) than in the general population. Chronic fatigue has multiple causes, including immunologic and psychological factors, sleeping problems, and alterations in the gut microbiome. In the Netherlands, there are more than 90.000 IBD patients, of which 63.000 (70%) patients are in remission at a given moment. Around 40% of patients in remission suffer from chronic fatigue. It is the biggest impediment in patients* daily lives. Fatigue reduces general well-being, quality of life (QoL), hampers social life, work productivity and may limit career perspectives. Very few patients experience resolution in fatigue, emphasizing the need for new interventions. Lifestyle interventions can modulate the majority of fatigue-driving factors. Hence, we hypothesize that a multimodal lifestyle intervention will reduce fatigue and consequently improve quality of life in patients with IBD who suffer from chronic fatigue.

Study objective

Objective: to investigate if a multimodal lifestyle intervention reduces chronic fatigue and improves quality of life in patients with IBD.

Study design

Study design: a multicenter, open-label, non-randomized, controlled trial.

Intervention

Intervention: a twelve-month multimodal lifestyle intervention provided by Voeding Leeft. The lifestyle intervention is a multimodal program that teaches participants the importance of an unprocessed and diverse diet (comparable with the Mediterranean diet), exercise, sleep, and stress reduction. It equips participants with the knowledge and practical skills to change and maintain their lifestyle permanently. The lifestyle intervention consists of three digital plenary and four smaller group sessions. The sessions will be organized over the course of six months. During the following six months participants can attend additional facultative sessions, which are organized every six to twelve weeks. These facultative sessions are aimed at encouragement of healthier habits implementation and (peer) support.

Study burden and risks

The risk of (serious) adverse events is low. However, participants may not tolerate certain food products and may suffer from abdominal pain, cramps diarrhea, or constipation. The alteration of diet may lead to weight loss. In patients with low to normal BMI, this may lead to an unwanted weight loss and might bring some participants in the underweight category. Therefore, BMI <18.5 kg/m2 is defined as one of the studies exclusion criteria.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2300RC
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2300RC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

o Adults (>=18 years old);

o Established IBD diagnosis (Crohn*s disease, Ulcerative colitis, or IBD-unclassified);
o Biochemical remission (fecal calprotectin <=150 mcg/g);
o Clinically significant fatigue (VAS 4-8 out of 10);
o Willing and able to attend digital group sessions as a part of the intervention.

Exclusion criteria

o Documented comorbidities such as severe cardiac failure (classified as NYHA 3-4), chronic kidney disease, myelodysplastic syndrome, Chronic Obstructive Pulmonary Disease (COPD), inherited metabolic diseases (e.g., phenylketonuria, mitochondrial or uric acid cycle pathologies), diabetes type 1;
o Documented history of malignancy within the last three years before inclusion except for dermatological cancers such as basal cell carcinoma or squamous cell carcinoma;
o Documented history of psychiatric diseases, eating disorders or addiction. Exception: patients with a history of depression and/or under treatment with antidepressants; however, at inclusion these patients must have a Hospital Anxiety Depression Scale (HADS) score <11 for the depression subscale;
o Documented familial hypercholesterolemia;
o Diabetes type 2 treated with insulin or other medications such as sulfonylureas, glinides, alpha-glucosidase inhibitors, etc. The only exception is biguanides*metformin.;
o BMI <18.5 or >35 kg/m2;
o Clinically significant anemia (Hb <7.0 mmol/l in females, Hb <8.0 mmol/l in males) with the exception of marginal normocytic or macrocytic anemia (MCV >100 fL and Hb >7.0 mmol/L for females and Hb >8.0 mmol/L for males) as a result of IBD-therapy related myelosuppression;
o Vitamin B12 deficiency (defined as a concentration below the lower reference range expressed in units that are used by the laboratory where the test has been performed);
o Folic acid deficiency (defined as a concentration below the lower reference range expressed in units that are used by the laboratory where the test has been performed);
o Iron deficiency (defined as ferritin <30 µg/l);
o Vitamin D deficiency (<30 nmol/l);
o History of prior bariatric surgery or upper gastrointestinal surgery such as Roux-Y reconstruction or (partial) gastrectomy due to benign or malignant pathologies;
o Pregnancy or active breastfeeding;
o Unwillingness to follow the lifestyle program, i.e. people that do not want to eat fish, vegans;
o Any change in systemic IBD-related medication in the last three months from the start of the intervention. Changes in medication dose are allowed up to one

month before the start of the intervention. Exception: changing the route of administration (e.g., switching from intravenous infliximab to subcutaneous infliximab) or change in therapy due to side effects such as an allergic reaction or cutaneous conditions.
o Recent major surgery, e.g. laparotomy in the last four weeks;
o Recent >2-week long hospitalization (in the last four weeks);
o Unable to speak and understand Dutch language;
o Participation in another study with lifestyle intervention or active consultation with a lifestyle coach on patient*s initiative;
o Previous participation in the IBD-tailored program by Voeding Leeft.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-04-2022
Enrollment:	106
Type:	Actual

Ethics review

Approved WMO

Date:	24-02-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	06-04-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	13-07-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	29-07-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
ClinicalTrials.gov	NCT05374967
CCMO	NL77752.058.21