The possible beneficial effects of Mindfulness-Based Cognitive Therapy (MBCT) in fatigued adult patients with Inflammatory Bowel Disease (IBD).

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1. To investigate the efficacy of MBCT on reducing fatigue 2. To investigate the efficacy of MBCT on reducing fatigue interference and anxiety and depression and improving IBD-specific quality of life, sleep quality, and labor participation, and to...

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

Summary

ID

NL-OMON45975

Source
ToetsingOnline

Brief title
MBCT-FAT-IBD

Condition

- Gastrointestinal inflammatory conditions

Synonym
Inflammatory Bowel Disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Fatigue, Inflammatory Bowel Disease, Mindfulness-Based Cognitive Therapy, RCT

Outcome measures

Primary outcome

The primary outcome is fatigue as assessed by the Checklist Individual Strength.

Secondary outcome

Secondary outcomes are: fatigue interference, anxiety, severity of depressive symptoms, IBD-specific quality of life, sleep quality, labor participation, satisfaction,

Additional several mediators, predictors to assess the effectivness of the interventions, demographic & clinical characteristics, treatment adherence by therapist and patients and non-study interventions will be assessed.

Study description

Background summary

Fatigue is highly prevalent among patients with IBD. MBCT is an evidence-based psychological treatment for reducing fatigue in patients with other chronic illnesses, but its effectiveness for patients with IBD needs more evidence. This longitudinal study aims to investigate the effectiveness of MBCT in reducing fatigue in IBD patients who are fatigued. Potential moderators and mediators of interventions will be examined.

Study objective

1. To investigate the efficacy of MBCT on reducing fatigue

2. To investigate the efficacy of MBCT on reducing fatigue interference and

anxiety and depression and improving IBD-specific quality of life, sleep quality, and labor participation, and to evaluate the benefits of the interventions from a patient perspective.

3. To investigate whether an increase in mindfulness and self-compassion, and a reduction in rumination, is associated with a reduction in fatigue

4. To investigate which IBD patients are more likely to respond positively to MBCT

Study design

The study is a multicenter two-arm RCT, with patients randomly assigned to MBCT or a waiting list control condition. As all patients in the current study are screened and have elevated levels of fatigue, all patients will be offered psychological treatment, either directly or three months after inclusion.

Intervention

A manualized intervention protocol including a detailed description of the content and homework assignments of each session has been developed (see Appendix I). MBCT is a highly structured intervention, that is internationally offered using a fixed program and week-to-week agenda, and is delivered in group form. The intervention consists of eight weekly sessions of 150 minutes led by experienced mindfulness trainers (licensed) who will be trained and supervised by dr. M. Schroevers. The first sessions focus on enhancing present-moment awareness of physical sensations, thoughts, emotions, and behavioral impulses and awareness of pleasant and unpleasant events. In the latter sessions, there is a greater focus on using mindfulness in dealing differently with distressing thoughts and emotions. For the proposed study, the protocol will have some adjustments to make them fatigue and IBD-specific, i.e. by adding IBD-specific and fatigue psycho-education. Patients receive a workbook with homework assignments and are expected to spend 30 minutes per day on these assignments. Patients will also receive audio CDs with mindfulness exercises.

Study burden and risks

The burden for patients consists of completing a questionnaire at four (MBCT group) or five (control group) points in time (time costs, 30 minutes each time). Patients receive treatment that has proven to be effective in the treatment of fatigue. Time costs: 8 weekly sessions of 150 minutes each and about 30 minutes of daily homework. We know of no negative effects of this treatment. Therefore, we consider the risks of this study to be low.

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

-Diagnosed with either Crohn*s disease or Ulcerative Colitis by a gastroenterologist
-Currently in remission, as defined by a score of < 4.99 on the mHealth Index Colitis Ulcerosa or a score of < 6.38 on the mHealth Index Crohn
-No expectation of a surgery in the upcoming three months
-Score on subjective fatigue subscale CIS (8 items) * 27
-Age * 18 and * 75 years at the time of study entrance
-Being able to attend eight weekly group sessions of 2,5 hours in the hospital
-Being able to read, write, and speak Dutch
-Written informed consent.

Exclusion criteria

- Severe cognitive, neurological or psychiatric co-morbidity that could interfere with patients* participation and/or warrant other treatment, including acute suicidal ideations or behavior, diagnosis of schizophrenia or history of psychotic complaints, bipolar disorder, severe personality disorder, or history of clinically significant drug abuse or substance dependence
- Pregnancy
- Anemia
- Change in IBD medication (including use of steroids) within 1 month before study entry.
- Currently receiving psychological treatment for fatigue or for psychological/psychiatric problems

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2016
Enrollment:	128
Type:	Actual

Ethics review

Approved WMO

Date:	12-09-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	28-06-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-09-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL58092.042.16