Mindfulness-based cognitive therapy to improve stress and reduce sleep in patients with inflammatory bowel disease

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Does Mindfulness-Based Cognitive Therapy (MBCT) reduce psychological distress and improve sleep quality and quality of life compared to treatment as usual (TAU) in patients with IBD?

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

Summary

ID

NL-OMON49598

Source
ToetsingOnline

Brief title
Mindfulness for IBD

Condition

- Gastrointestinal inflammatory conditions
- Anxiety disorders and symptoms
- Lifestyle issues

Synonym
Colitis Ulcerosa, Crohn's disease, Inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Inflammatory bowel disease, Mindfulness, psychological distress, sleep

Outcome measures

Primary outcome

Primary outcome will be psychological distress according to the Hospital Anxiety and Depression Scale (HADS).

Secondary outcome

Secondary outcomes will be:

- Sleep quality/regularity (wearable sleep EEG: the iBand+ and the Fitbit activity tracker) and fatigue (FACIT-F).

- IBD-specific secondary outcomes will be IBD-related quality of life (IBDQ), perceived control over IBD (IBD-control questionnaire).

- Clinical secondary outcomes will be fecal calprotectin, c-reactive protein levels (both assessed in accordance with regular medical procedures), clinical disease activity (Harvey Bradaw Index for CD, the Simple Clinical Colitis Activity Index for UC), and relapse into IBD-related flares.

- General secondary outcomes will be repetitive negative thinking (PTQ) , mindfulness skills (FFMQ-SF), self-compassion skills (SCS-SF), and positive mental health (MHC-SF).

- Costs (TIC-P) and utilities (EQ-5D-5L) will be investigated to explore cost-effectiveness. Lastly, qualitative interviews which focus on usefulness

and feasibility of MBCT will be performed.

Study description

Background summary

Inflammatory bowel diseases (IBD) mainly consisting of Crohn*s disease (CD) and ulcerative colitis (UC) are chronic inflammatory conditions of the gastrointestinal tract. Many IBD patients suffer from psychological distress, reduced sleep quality and fatigue, for which only limited treatment options are available. This is associated with reduced quality of life and increased healthcare costs. The incidence of IBD is increasing worldwide. As mindfulness seems to improve psychological distress and quality of life in IBD and improves sleep, MBCT might target three important health problems in patients with IBD. In addition, findings from this study may serve as a model for other chronic conditions.

We hypothesize that MBCT+TAU will be more effective than TAU alone in reducing stress in IBD patients with disease remission. In addition, we hypothesize that MBCT will be superior to TAU with regard to improvements in sleep quality/regularity and fatigue, and on IBD-related outcomes: IBD-related quality of life, and perceived control over IBD, clinical indicators (fecal calprotectin, c-reactive protein levels, Harvey Bradaw Index for CD, and the Simple Clinical Colitis Activity Index for UC), and relapse into IBD-related flares. Furthermore, we hypothesize that MBCT will improve general health outcomes: repetitive negative thinking, mindfulness skills, self-compassion skills, and positive mental health.

Study objective

Does Mindfulness-Based Cognitive Therapy (MBCT) reduce psychological distress and improve sleep quality and quality of life compared to treatment as usual (TAU) in patients with IBD?

Study design

A randomized, parallel multicenter, controlled clinical trial with a treatment as usual (TAU) control group and Mindfulness-based cognitive therapy (MBCT)+TAU intervention group.

Intervention

The intervention group will receive Mindfulness-Based Cognitive Therapy (MBCT) in addition to treatment as usual (TAU). MBCT consists of 8 weekly sessions of

2,5 hours each, a silent day and home practice. It teaches formal and informal meditation exercise and cognitive behavioral skills. The control gorup will receive TAU. which will consist of treatment according to Dutch and European IBD treatment guidelines. TAU mainly focuses on pharmacological and surgical disease control, and prevention of complications.

Study burden and risks

The patients will follow the 8 week MBC program with weekly 2.5 hours sessions and are encouraged to practice MBCT in between. Furthermore, they will be asked to fill in online questionnaires before the intervention (basesline) and at 3, 6, 9 and 12 months which will take approximately 30-60 minutes each. Objective sleep quality and sleep regularity will be measured immediately before and after the intervention (baseline and 3 months), for 14 consecutive nights each, in a naturalistic home-based setting using the novel wearable sleep EEG recorder iBand+, recently developed by the industry partner Arenar B.V. Thereby, sleep quality and regularity will also be measured during the 8 weeks MBCT training, in a naturalistic home-based setting using the Fitbit activity tracker. Time investment for the group receiving TAU is 6.5 hours and for the group receiving MCT + TAU is 32.5 hours.

The risks associated with participated are expected to be low. Participants learn mindfulness skills to cope with psychological distress in a more effective way. This may include increased awareness of difficult emotions, which may at first be confronting or overwhelming. This is a major topic that will be discussed during MBCT and if participants show a clear increase in symptoms, additional guidance will be offered. Participants are encouraged to respect their boundaries (both physical and psychological) and are always free to quit or adapt the practice as needed.

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

Confirmed IBD diagnosis of Crohn*s disease (CD), Ulcerative colitis (UC) or Indeterminate colitis (IC)
Current IBD remission (Calprotectin < 250 mg/kg) since at least three months
Hospital Anxiety and Depression Scale-score of ><=11, indicating at least mild levels of psychological distress.
Age of 18 or older
Taking no IBD medication or on a stable dose of 5-ASA products, immunosuppressive medication, or biologics for at least three months prior to enrollment

Exclusion criteria

Severe psychiatric disorders (e.g. acute suicidality, psychosis)
Current alcohol or drug dependency
Untreated anemia
Prior participation in an 8-week MBSR or MBCT-programme

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-07-2021
Enrollment:	136
Type:	Actual

Ethics review

Approved WMO Date:	20-04-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-06-2021
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
ClinicalTrials.gov	NCT04646785
CCMO	NL75762.091.20

Study results

Date completed:	03-10-2023
Actual enrolment:	142