

The effect of standard mindfulness based stress reduction (MBSR) on quality of life and symptom severity in patients with irritable bowel syndrome.

Published: 16-04-2013

Last updated: 25-04-2024

The research questions this study aims to answer are: What is the effect of a Mindfulness Based Stress Reduction (MBSR) training on IBS in terms of quality of life. It is hypothesised that participation in a MBSR-training will improve quality of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON38938

Source

ToetsingOnline

Brief title

The effect of Mindfulness on irritable bowel syndrome.

Condition

- Gastrointestinal signs and symptoms
- Somatic symptom and related disorders

Synonym

mucous colitis, spastic colon

Research involving

Human

Sponsors and support

Primary sponsor: Kennemer Gasthuis

Source(s) of monetary or material Support: geen

Intervention

Keyword: Irritable bowel syndrome, MBSR, Mindfulness, quality of life

Outcome measures

Primary outcome

Main study parameter is the statistical change in quality of life as measured with the Irritable Bowel Syndrome Quality of Life questionnaire (IBS-QOL).

Secondary outcome

Secondary parameters are the statistical change in symptom severity as measured with the Irritable Bowel Syndrome - Symptom Severity Scale (IBS-SSS).

Study description

Background summary

Quality of life is shown to be low in patients with irritable bowel syndrome (IBS) while a pathophysiological mechanism behind the syndrome has never been demonstrated. There is a considerable body of evidence for socio-psychological factors having some role in IBS. Catastrophizing, a maladaptive cognitive coping style characterized by ruminations about the significance of symptoms, also seems to play a part. Patients with IBS, through a learning process and under the influence of state and trait characteristics, are not only hypervigilant or hypersensitive regarding interoceptive (i.e. visceral) signals, but are also prone to catastrophize these signals. Mindfulness increases sensory processing of interoceptive signals and decreases emotional and cognitive processing of these signals, thereby theoretically reducing catastrophizing.

Study objective

The research questions this study aims to answer are: What is the effect of a Mindfulness Based Stress Reduction (MBSR) training on IBS in terms of quality

of life. It is hypothesised that participation in a MBSR-training will improve quality of life in IBS-patients. Secondary this study aims to prove an effect of mindfulness on severity of symptoms in IBS, the hypothesis being that participation in MBSR lowers the severity of IBS symptoms.

Study design

The study design is a Randomized Controlled Trial (RCT).

Intervention

The intervention group will receive a ten week Mindfulness program according to a standard protocol (MBSR), administered by a certified Mindfulness instructor. The waiting list group will be tested (i.e. fill out a set of questionnaires two times) while waiting for treatment at a later date.

Study burden and risks

The intervention protocol includes eight weekly training sessions of 135 minutes each and one four-hour intensive training session (retreat). Furthermore participants are required to commit to self-study and exercises for approximately one hour each day during the training. Research assessment for all participants consists of four questionnaires filled out two (control-group) or three times (Intervention-group) during the study the total time needed to fill out these forms is approximately 30-45 minutes each assessment. No adverse events are to be expected.

Contacts

Public

Kennemer Gasthuis

Boerhaavelaan 22
Haarlem 2035 RC
NL

Scientific

Kennemer Gasthuis

Boerhaavelaan 22
Haarlem 2035 RC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- (1) IBS diagnosis by the gastroenterologist through Rome III criteria (Nederlands Huisartsen Genootschap, 2011)
- (2) Age 18-65 years
- (3) Sufficient comprehension of the Dutch language
- (4) Willingness to attend an eight week training program consisting of 135 contact minutes per week and one hour of self-study a day
- (5) Willingness to fill-out the questionnaires used to assess the outcome measurements;
- (6) An obtained signed informed consent.

Exclusion criteria

- (1) Diagnoses of mental illness with psychosis
- (2) A psychiatric illness of which the treatment takes priority over the treatment of IBS with psychological methods.
- (3) A history of in-patient psychiatric treatment within the last two years
- (4) A history or current diagnosis of inflammatory bowel disease or gastrointestinal malignancy
- (5) A malignant co morbidity
- (6) Active liver or pancreatic disease
- (7) A history of abdominal trauma or surgery involving gastrointestinal resection
- (8) Pregnancy

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:	Recruitment stopped
Start date (anticipated):	26-08-2013
Enrollment:	42
Type:	Actual

Ethics review

Approved WMO	
Date:	16-04-2013
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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

CCMO

ID

NL43532.094.13