

Mindfulness-based stress reduction in patients with Irritable Bowel Syndrome (IBS)

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32553

Source

ToetsingOnline

Brief title

MBSR in IBS

Condition

- Other condition
- Gastrointestinal motility and defaecation conditions

Synonym

functional intestinal disease, irritable bowel

Health condition

functionele buikklachten

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg

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

Intervention

Keyword: irritable bowel syndrome (IBS), mindfulness, stress

Outcome measures

Primary outcome

subjective stress levels (questionnaire)

Secondary outcome

severity of IBS symptoms

Study description

Background summary

The Irritable Bowel Syndrome (IBS) is the most prevalent conditions in the field of gastroenterology, and is characterised by stomach pains, together with changes in defecation patterns, without the presence of physical deviations.

A treatment is not available at the moment, and there is no evidence to indicate a pathophysiological mechanism. One of the hypothesised mechanisms is the presence of emotional stress. However, psychotherapy or behavioural therapy have not yet been succesful in treating IBS symptoms.

Study objective

the aim of the current pilot investigation is to examine the effectiveness of mindfulness based stress reduction in reducing stress levels in IBS patients, as well as the effects of the training on IBS symptom severity and quality of life in these patients.

Study design

This pilot intervention study has an open randomised design with a treatment group and a waiting list control group. The training period is 2 months. Before and after the intervention both groups fill out a questionnaire regarding IBS

symptoms and psychological factors. When the intervention group is done, the training is given to the waiting list control group. They fill out the questionnaires again, both at the start and end of the intervention.

Intervention

The intervention is mindfulness based meditation. Participants learn to have an open and nonjudgmental way of viewing events that are happening, including their own disturbing thoughts and feelings. They learn not to identify with these mental events, but to just observe them nonjudgmentally and let them go. This is accomplished by means of simple meditation techniques, such as zazen (mindful sitting and breathing), during which a sensory stimulus, such as the movement of breath, is used as a anchor in the present moment which is attended to. At the same time one is open for other events that take place, especially mental events, which are noticed and let go. The training is provided in a group of 20 individuals, while another group serves as a waiting-list control group. The training consists of four sessions of four hours with the following time intervals in between: 1, 2, and 2 weeks. One of the important behavioral goals of the training is to bring about daily meditation practice in participants, which is continued after the training has ended. During the training, participants will continue their usual treatment.

Study burden and risks

There's no risk involved in this study

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

female, IBS diagnosis

Exclusion criteria

Impaired proficiency of the Dutch language, psychiatric comorbidity, impairing somatic comorbidity

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Completed

Start date (anticipated):	01-02-2009
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO	
Date:	15-12-2008
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL25272.008.08