

Efficacy of online cognitive behavioral therapy on symptoms and quality of life with irritable bowel syndrome

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29140

Source

Nationaal Trial Register

Brief title

TBA

Health condition

Irritable Bowel Syndrome

Sponsors and support

Primary sponsor: None

Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

IBS-symptoms

The primary outcome of this study is IBS-symptoms, as measured with the Irritable Bowel Severity Scoring System (IBS-SSS), developed by Francis, Morris and Whorwell (1997).

Secondary outcome

IBS-quality of life, as measured with the Irritable Bowel Syndrome-Quality of Life Measure (IBS-QOL), developed by Patrick, Drossman, Frederick, Dicesare en Puder (1998).

Gastrointestinal specific anxiety (GSA), as measured with the Visceral Sensitivity Index (VSI), developed by Labus, Bolus, Chang, Wiklund, Naesdal, Mayer en Naliboff (2004).

Patient demographics: gender, age, education, years and months since debut IBS-symptoms and diagnosed IBS, treatment history, medical health.

Treatment expectation (one question), treatment and therapist satisfaction, suggestions for improving the treatment.

Participants who decide to stop the treatment, will be asked for what reason.

Study description

Background summary

The Irritable Bowel Syndrome is a chronic gastrointestinal affliction and with a prevalence of 10-20% one of the most diagnosed gastrointestinal conditions (in the general population). Physical as well as psychological factors could be in play in IBS. Besides being a burden for the patient, it could also be a burden for society. Multidisciplinary guidelines for IBS aim to minimize restrictions in daily life as treatment goal. Given that anxiety for symptoms is seen as a maintaining factor in IBS, this is the key feature of the treatment.

The proposed study is a randomized controlled trial (RCT), based on a guided online treatment for IBS which has been previously studied by Ljótsson et al., 2010, namely cognitive behaviour therapy (CBT) including exposure- en mindfulness exercises. Besides a decrease of IBS-symptoms a decrease of restrictions in daily life and anxiety is the treatment goal. Hypotheses are that the guided online treatment, based on CGT (exposure- en mindfulness exercises) as compared to a waiting list control group will leads to 1) a bigger decrease in IBS-symptoms, 2) a bigger increase in IBS-specific quality of life, 3) a bigger decrease in IBS- specific anxiety. Finally, it is expected that IBS- specific anxiety has a mediating effect in the treatment results.

Study objective

Hypotheses are that the guided online treatment, based on CGT (exposure- en mindfulness exercises) as compared to a waiting list control group will leads to 1) a bigger decrease in IBS-symptoms, 2) a bigger increase in IBS-specific quality of life, 3) a bigger decrease in IBS-specific anxiety. Finally, it is expected that IBS- specific anxiety has a mediating effect in the treatment results.

Study design

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Intervention

Guided online treatment, based on CGT (exposure- en mindfulness exercises)

Contacts

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Eligibility criteria

Inclusion criteria

- 18 years and over
- IBS diagnosed by general practitioner or physician, meeting the Rome-IV-criteria
- Having access to internet, a tablet/computer/laptop/telephone
- Proficient in the Dutch language

Exclusion criteria

- Medical intervention for IBS started in the 6 months preceding
- Already, for any reason, in concurrent psychological treatment
- Bowel disease other than IBS

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	08-01-2020
Enrollment:	66
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Not applicable	
Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 48448
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8275
CCMO	NL68331.078.19
OMON	NL-OMON48448

Study results