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

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Primary objective:Is guided online treatment, based on CGT with mindfull- and exposure exercises, with minimal patient contact, effective for IBS-patients as compared to a waiting list?Secondary objectives: Will the guided online treatment lead to...

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON48448

Source
ToetsingOnline

Brief title
Online CGT for IBS

Condition

- Gastrointestinal conditions NEC
- Somatic symptom and related disorders

Synonym
Irritable bowel

Research involving
Human

Sponsors and support

Primary sponsor: Medische-Psychologie.nl
Source(s) of monetary or material Support: Medische-Psychologie.nl

Intervention

Keyword: Cognitive behavioural therapy, E-health, IBS, Irritable bowel syndrome

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

Primary objective:
Is guided online treatment, based on CGT with mindfull- and exposure exercises, with minimal patient contact, effective for IBS-patients as compared to a waiting list?

Secondary
objectives:

Will the guided online treatment lead to a significant improvement of in IBS-specific quality of life, as compared to a waiting list?
Will the guided online treatment lead to a significant decrease of IBS-specific anxiety, as compared to a waiting list?
Is IBS- specific anxiety a mediator in the treatment effect in terms of IBS-symptoms?

Study design

The study is a randomized controlled trial (RCT), with pre- and post-test (ten weeks between) and a waiting list as control group.

Intervention

The treatment group receives an online CGT-treatment, based on mindfulness- and exposure-exercises, with a duration of ten weeks and consisting of five steps. The last step (exposure) takes six weeks. Every week the participant gets access to a new step consisting of psycho education (video and text) and homework. Once per week (at least), there will be contact at email for questions and the homework.
The control group is a waiting list. After ten weeks, the participants are offered the same treatment as the treatment condition.

Study burden and risks

Risks during the study are not expected and participants are expected to benefit from the treatment.

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

* 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 CBT Six months or less started with
another (medical) intervention for IBS
* 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)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-09-2019
Enrollment:	66

Type:	Anticipated

Ethics review

Approved WMO Date:	18-10-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29140
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL68331.078.19
OMON	NL-OMON29140