The effect of EMDR on abdominal pain in patients with IBS

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24398

Source
Nationaal Trial Register

Brief title
EMDR4IBS

Health condition

Irritable Bowel Syndrome

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: The trial is done as part of the curriculum for trainees to become a 'Psychologist Specialist' (opleiding Klinisch Psycholoog, RINO Groep Utrecht).
A research grant (5000 euros) has been awarded by the Vereniging EMDR Nederland (VEN).
Another research grant will be applied for at the sience-desk at the Diakonessenhuis Utrecht.

Intervention

Outcome measures

Primary outcome

Pain score 0-10 reported by subject; reported daily during 2 weeks, three times: directly after

inclusion (T1), 6 weeks after that (T2, after treatment period for the treatment group) and 10 weeks after that (T3,follow up). In total 42 reported scores.

Secondary outcome

Diary reports (exactly like the primary outcome) for:
- two IBS complaints other than pain (chosen by the subjects as the most burdensome)
- hindrance experienced by subjects (caused by IBS) in two valued activities (chosen by subjects as 'most interfered with')

And at the end of all three diary periods:

Total score on the Irritable Bowel Syndrome- Severity Scoring System (IBS-SSS)

Total score on the Irritable Bowel Syndrome- Quality of Life measurement (IBS-QOL)

Adequate relief question

Study description

Background summary

Many patients with Irritable Bowel Syndrome (IBS) suffer from severe and frequent abdominal pain. Eye Movement Desensitization and Reprocessing (EMDR) is an evidence based, standard treatment for PTSD and for psychopathology in which unresolved unpleasant experiences play a role in the development and / or maintenance of complaints. In recent years, increasing scientific evidence has been found that EMDR as a treatment can also be effective for chronic pain. To date, no scientific research has been conducted to investigate the effect of EMDR on abdominal pain (in IBS). Results with individual patients in clinical practice are promising.
It is hypothesized that EMDR treatment will reduce abdominal pain in patients with Irritable Bowel Syndrome (IBS). In addition, the effect of EMDR treatment on IBS complaints other than pain is examined, as well as the effect of EMDR treatment on the quality of life of patients with IBS.

It is a randomized clinical trial, in which the control group is 'wait list' (e.g. receives treatment after their participation in the trial has finished).

Study objective

Abdominal pain in patients in the intervention group (EMDR) will be reduced more than patients in the control group.

Study design

as described above (see: 'primary outcome' and 'secondary outcome')

Intervention

Intake and 6 weekly sessions of 90 minutes of EMDR standard protocol

Contacts

Public
Diakonessenhuis
Baukje Wertheim

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Eligibility criteria

Inclusion criteria

Adult
Meets ROME IV criteria for IBS
Pain intensity score on IBS-SSS at least 60
Reports on IBS-SSS a frequency of pain at least 5 out of 10 days

(IBS-SSS= Irritable Bowel Syndrome- Severity Scoring System)

Exclusion criteria

Other somatic conditions associated with abdominal pain such as ulcerative colitis and Crohn's disease.
Other pain symptoms that are more prominent than abdominal pain.
Insufficient command of the Dutch language to complete questionnaires (or other circumstances that seriously hinder communication).
Age under 18 or above 65
Psychiatric problems that require immediate treatment (such as psychosis, depression, suicidality)

Ongoing psychotrauma treatment.
Substance abuse
Pregnancy (to prevent confusion about the cause of abdominal sensations).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-08-2020
Enrollment:	34
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	28-08-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49387
Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8894
CCMO	NL71740.100.20
OMON	NL-OMON49387

Study results