The effect of Eye Movement Desensitisation and Reprocessing (EMDR) on abdominal pain in patients with Irritable Bowel Syndrome (IBS).

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Our goal is to investigate the effect of EMDR treatment on abdominal pain in patiënts with Irritable Bowel Syndrome. In addition we will investigate the effect of EMDR treatment on other IBS physical complaints and on patients' experienced...

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

Summary

ID

NL-OMON49387

Source
ToetsingOnline

Brief title
EMDR for IBS

Condition

- Gastrointestinal conditions NEC
- Anxiety disorders and symptoms

Synonym
Irritable Bowel, Irritable Bowel Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht
Source(s) of monetary or material Support: Onderzoek in het kader van opleiding tot Klinisch Psycholoog. Er wordt subsidie aangevraagd bij de Vereniging EMDR Nederland.

Intervention

Keyword: abdominal pain, EMDR, Irritable Bowel Syndrome (IBS)

Outcome measures

Primary outcome

The primary outcome measure is the severity of the abdominal pain as measured by diary registration. At all three measuring times (T1, T2, T3), during two weeks, patients are asked to rate their abdominal pain on a Likert scale (0-10). The calculated mean over all rated days will be used as primary outcome measure.

Secondary outcome

* Severity of IBS complaints

1) diary measurements like described above for pain are taken for two other IBS complaints (specifically, the two most troublesome IBS complaints). The calculated mean over all rated days will be used as outcome measure.

2) total score on the Irritable Bowel Syndrome-Severity Scoring System

* Quality of Life

1) at T1, T2 and T3 diary measurements patients are asked to rate the burden they experience due to their IBS complaints in two valued activities (Likert scale 0-10). The calculated mean over all rated days will be

used as outcome measure.

2) total score on the Irritable Bowel Syndrome- Quality of Life measure.

* Experienced relief of complaints

- Adequate Relief Question

Study description

Background summary

Many patients with Irritable Bowel Syndrome suffer from severe and frequent abdominal pain. Eye Movement Desensitisation and Reprocessing (EMDR) is a standard treatment for PostTraumatic Stress Disorder and for psychopathology caused or maintained by not fully processed memories. In the last few years increasing scientific evidence shows that EMDR can be effective to alleviate chronic pain. So far, there heven't been any scientific studies into the effect of EMDR on abdominal pain. Our hypothesis is that EMDR-treatment will diminish abdominal pain in patients with Irritable Bowel Syndrome.

Study objective

Our goal is to investigate the effect of EMDR treatment on abdominal pain in patiënts with Irritable Bowel Syndrome. In addition we will investigate the effect of EMDR treatment on other IBS physical complaints and on patients' experienced quality of life,

Study design

A Randomized Controlled Trial in a clinical setting, with two arms (treatment and control) and three measurements taken (T1 at the start, T2 after treatment (controls: 8 weeks after T1), and T3 after 3 months follow up).

Intervention

Patients in de treatment condition (after intake/case conceptualization) receive 6 weekly sessions of EMDR treatment (each 90 lasting minutes).

Study burden and risks

EMDR is an evidence based treatment that is acknowledged in (inter)national guidelines. It has been frequently applied without negative consequences in several different patient populations. Activated memories , and accompanying cognitions, emotions and physical sensations may linger after an EMDR session, but this is part of the psychological process and in effect useful.
Participants receive their treatment free of charge. Patients in de control group will be offered appropriate treatment after their last measurements (T3).

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

Adult (18-65 yrs old)
Meets ROME IV criteria for Irritable Bowel Syndrome
Severe and frequent abdominal pain (as measured by Irritable Bowel

Syndrome-Severity Scoring System).

Exclusion criteria

Insufficient knowlegde of Dutch language (to fill out questionnaires, or for communication)
Psychiatric problems that demand immediate treatment
Ongoing treatment for psychotrauma.
Somatic disorders that cause abdominal pain such as Colitis and Crohn's disease.
Substance abuse

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	30-11-2020
Enrollment:	34
Type:	Actual

Ethics review

Approved WMO Date:	29-05-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	16-11-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-02-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-12-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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: 24398
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL71740.100.20