Investigating the effect of Eye Movement Desensitization and Reprocessing (EMDR) on fibromyalgia: a ten times replicated multiple-baseline experimental case study

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This study will be the first controlled study specifically investigating the effect of EMDR on FM pain and additional physical symptoms.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON50804

Source
ToetsingOnline

Brief title
EMDR4FM

Condition

- Joint disorders
- Somatic symptom and related disorders

Synonym
chronic pain syndrome, Fibromyalgia

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Noord-Holland-Noord
Source(s) of monetary or material Support: GGZ Noord-Holland-Noord,Vereniging EMDR Nederland

Intervention

Keyword: chronic pain, EMDR, fibromyalgia, psychotherapy

Outcome measures

Primary outcome

Daily data are collected of the primary parameter which is pain intensity.

Secondary outcome

Secondary parameters are stiffness in muscles and joints, fatigue, the impact of pain on daily life, the impact of pain on sleep and a selection of four PTSD symptoms.

Exploratory analysis:

At specific time points data will be collected of the impact of FM complaints on daily life, PTSD symptoms, psychiatric symptoms and functioning in general, depressive symptoms, central sensitization symptoms and the patient impression of change. The time points are at the start of the baseline, at the end of the baseline period which corresponds to the start of the intervention, directly after the EMDR treatment, one month after the EMDR treatment and three months after the EMDR treatment.

Study description

Background summary

Fibromyalgia (FM) is a disabling chronic pain syndrome characterized by multi-site pain, stiffness, fatigue and sleeping problems. Symptoms of central sensitization are common in FM as are post-traumatic stress symptoms. Eye Movement Desensitization and Reprocessing Therapy (EMDR) is an evidence-based treatment for post-traumatic stress disorder (PTSD). Evidence is mounting that chronic pain can also be treated with EMDR. However, to date no controlled studies have been conducted specifically targeting EMDR for FM. Based on previous research it is hypothesized that EMDR may reduce pain intensity in patients with FM.

Study objective

This study will be the first controlled study specifically investigating the effect of EMDR on FM pain and additional physical symptoms.

Study design

A non-concurrent, multiple-baseline single-case experimental design (SCED) which will be replicated ten times. Participants are randomly assigned to one of three time series and also the start of the intervention within the time series is randomly determined.

Intervention

EMDR therapy consists of seven sessions of 90 minutes in total, performed according to the EMDR standard protocol. EMDR focuses on processing traumatic memories and pain-related memories.

Study burden and risks

If the therapy is effective, pain intensity decreases, additional physical complaints of FM decrease and patients experience less discomfort from their pain in daily life. EMDR therapy is an evidenced based treatment for PTSD and reduction of posttraumatic stress favors recovery of physical complaints. Participating in the study includes attending the EMDR therapy sessions (seven times 90 minutes), two conversations for inclusion (two times 60 minutes consisting of one telephone conversation and one face-to-face conversation), daily registration of complaints (about two minutes per day, including registering possible daily medication intake) via a smartphone application, and completing the questionnaires (about 20-30 minutes at five specific time points during the study). If necessary, a test of intellectual functioning will be done at before inclusion, which takes 2-3 hours. The daily registration and study will take a minimum period of 15 weeks to a maximum period of 17 weeks. At three-months follow-up patients will be asked to register daily for 14 days.

In total, this makes a total burden of 22 to 25 hours with an estimated total of filling in daily registrations and questionnaires of around 9 hours. EMDR sessions can be emotionally intense, but never are as challenging as living with unprocessed (traumatic) pain related memories. There are no risks associated with EMDR therapy.

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

Inclusion criteria:
1) a medical diagnosis of fibromyalgia
2) age of 18 years and older
3) an average pain intensity score in the past week of >= 7 on a Numerical Rating Scale for Pain

4) sufficient understanding of the Dutch language verbally and in writing, in order to be able to participate
5) willingness to participate in the study (as indicated by the signed informed consent)

Exclusion criteria

Exclusion criteria:
1) an acute condition of psychosis or bipolar disorder
2) an acute suicidal risk
3) an IQ < 80
4) substance dependency
5) stable on use of medication. Medication was not started less than 3 months ago (e.g. psychotropic drugs, analgetics or other medication with effect on pain or symptoms of fibromyalgia). If medication was started more than 3 months ago, medication can be continued. We will ask patients to keep their medication prescriptions as stable as possible during the study.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-01-2022
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	28-09-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL76917.029.21