EMDR in the treatment of Chronic Fatigue Syndrome (CFS): can EMDR make the perception of fatigue less negative? A sequential randomized and replicated single-case experimental phase design with multiple measurements.

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Primary Objective: The main aim of this study is to investigate if EMDR diminishes negative associations with fatigue in CFS-patients who follow CBT.Secondary Objective(s): Second, we will investigate if EMDR strengthens the belief of the patient...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Somatic symptom and related disorders
Study type	Interventional

Summary

ID

NL-OMON42629

Source
ToetsingOnline

Brief title
EMDR in the treatment of CFS: a single case experiment

Condition

- Somatic symptom and related disorders

Synonym
Chronic Fatigue Syndrome; CFS

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chronic, EMDR, Fatigue, Fatigue Syndrome, Perception

Outcome measures

Primary outcome

Primary study parameter is negative associations with fatigue; these are measured by daily scores on the adapted FQL-items. Participants will be asked to click on a line of 0-10cm: *To what extent does the following adjective fit your experienced fatigue? *.

Three adjectives will be chosen from the baseline assessment FQL-scores (T0) of the individual participant.

Secondary outcome

Secundary study parameters are:

The cognition that one is recovered from CFS; this is measured daily by asking the participant to click on a line ranging from of 0-10 cm (not credible at all * completely credible): *How credible does it feel for you to say *I am recovered from CFS*?

The experienced fatigue; this is measured daily by asking the participant to click on a line ranging from of 0-10 cm (not fatigued at all * extremely fatigued): *I feel today: *.

Study description

Background summary

CFS can be effectively treated with Cognitive Behaviour Therapy (CBT) but there is room for improvement. Although the majority of the patients does benefit from therapy and no longer meets the CDC-criteria for CFS, only a subgroup fully recovers. Patients who do not fully recover, still consider themselves as CFS-patients and still have a negative perception of fatigue. There are no treatment options for patients who do not fully recover in CBT.
From both clinical practice and learning theory we hypothesize that negative experiences with being severely fatigued can cause persistent negative associations with fatigue, which might hinder full recovery. Eye Movement Desensitization and Reprocessing (EMDR) is a safe and effective treatment for negative memories. It is a recommended treatment for patients with Post traumatic Stress Disorder (PTSD). EMDR is also used to treat negative memories in patients with Chronic Pain. There is some evidence that this can decreases pain and negative emotions about pain.
In this study we will experimentally test if EMDR can change negative associations about fatigue. We will also test if EMDR diminishes the experienced fatigue and stregthens the belief of the patient that he/she is recovered from CFS
The goal is to determine if EMDR might be an additional treatment option for CFS-patients who do not fully recover with CBT.

Hypotheses: Eye Movement Desensitization & Reprocessing (EMDR) changes negative associations with fatigue. EMDR diminishes the experienced fatigue. EMDR stregthens the belief of the patient that he/she is recovered from CFS.

Study objective

Primary Objective:
The main aim of this study is to investigate if EMDR diminishes negative associations with fatigue in CFS-patients who follow CBT.

Secondary Objective(s):
Second, we will investigate if EMDR strengthens the belief of the patient that he/she is recovered from CFS. In addition to this we will investigate if EMDR decreases the experienced fatigue.

Study design

This is a simultaneously replicated, randomised single case experiment. The purpose of this design is to test causal relationships between independent and

dependent variables.

Intervention

Participants will receive five one-hour sessions of EMDR, following an adapted protocol. The sessions will be held within a two-week period.

Study burden and risks

There are no or only minimal risks involved in pausing the regular CBT-treatment for 28-42 days because this treatment is in the latest stage and in this group of patients a stagnation is noticed.
There are no or only minimal risks involved in following the EMDR-intervention. The EMDR therapists are well trained and will be supervised by an EMDR-expert. Possible minor side-effects will usually disappear within a few days.
It can be a burden for patients to fill in the daily questionnaires. These are short (5-10 minutes) and time and way of administration is agreed upon between patient and research team.
Participants have substantial potential benefits by following this extra intervention because they are not completely recovered by following their existing 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

Female, age of 18 * 65 years
Diagnosed with CFS; CDC-criteria met at start of CBT-treatment
Having received CBT for CFS; experienced success in increasing activities
Negative associations with fatigue (FQL at least one negative subscale >25%)
Not convinced that one is recovered from CFS: score * 6 on scale 0 * 10 *I am recovered from CFS*:

Exclusion criteria

Use of psychotropic drugs or daily use of painkillers;
Co-morbid psychiatric disorder (DSM-IV-R) at baseline assessment before start of CBT

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO Date:	09-09-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL52993.091.15