Epilepsy and anxiety- targeting a vicious cycle:
Comparison of cognitive behavioural therapy (CBT), eye movement desensitization and reprocessing (EMDR) therapy and wait-list in targeting epilepsy-related anxiety and posttraumatic stress

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Case series study (10 persons with epilepsy-related anxiety symptoms and/ or posttraumatic stress):-To examine the potential effects of EMDR therapy in terms of reducing anxiety, from pre-treatment to post-treatment. Randomized controlled trial (75…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Seizures (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON48908

Source
ToetsingOnline

Brief title
CBT and EMDR in the treatment of epilepsy-related anxiety

Condition

- Seizures (incl subtypes)
- Anxiety disorders and symptoms

Synonym
epilepsy; convulsion

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anxiety, Cognitive behavioural therapy, Epilepsy, Eye movement desensitization and reprocessing

Outcome measures

Primary outcome

The primary outcome measures are:

Anxiety:

-Hospital Anxiety and Depression Scale- anxiety

-Symptom Checklist-90-R- anxiety

-Severity of PTSD symptoms (PTSD Checklist for Diagnostic and Statistical

Manual of Mental Disorders-Fifth Edition)

-Self-reported anxiety (diary)

Physiological stress:

-Electrocardiography (ECG) heart rate variability (standard deviation of the NN

(R-R) intervals, low and high frequency activity)

Secondary outcome

De secundary outcome measures are:

• Self-reported number of seizures (diary)

• Seizure severity (Liverpool Seizure Severity Scale 2.0)

• Quality of life (Quality of Life in Epilepsy - 31)

• Number of sessions needed to reduce the level of subjective distress related

to the most stressful memory/scenario to zero

Other study parameters/ possible confounders are:

• Demographics (General questionnaire)

• Treatment expectation (General questionnaire)

• Disease characteristics (General questionnaire)

• Personality (NEO Five-Factor Personality Inventory)

• Depression (Hospital Anxiety and Depression Scale- depression)

• Chronic everyday stress (Everyday Problem Checklist)

• Psychopathology (Symptom Checklist-90-R)

Study description

Background summary

Anxiety disorders are present in about 14-25% of people with epilepsy. The unpredictable and uncontrollable nature of epilepsy often results in anxiety and posttraumatic stress symptoms, which may provoke new seizures. Psychological interventions may be beneficial to break this vicious cycle. The current study aims to compare cognitive behavioural therapy (CBT), eye movement desensitization and reprocessing (EMDR) therapy and a wait-list condition in treating posttraumatic stress and/ or anxiety symptoms related to epilepsy.

Study objective

Case series study (10 persons with epilepsy-related anxiety symptoms and/ or posttraumatic stress):
-To examine the potential effects of EMDR therapy in terms of reducing anxiety, from pre-treatment to post-treatment.

Randomized controlled trial (75 persons with epilepsy-related anxiety symptoms and/ or posttraumatic stress):
-To examine the efficacy of CBT and EMDR therapy in comparison to a wait-list condition in terms of reducing anxiety and physiological stress and consequently in reducing seizure frequency and severity and improving quality of life, from pre-treatment to post-treatment.

-To compare the efficiency of CBT and EMDR therapy in persons with epilepsy-related anxiety symptoms and/ or posttraumatic stress, in terms of the number of sessions needed to reduce the level of subjective distress related to the most disturbing memory or scenario.

Study design

A case series study with repeated measurements will first be conducted, followed by a randomized controlled trial with a repeated measures design.

Intervention

CBT and EMDR therapy will be delivered using a maximum of 10 sessions of 90 minutes by experienced therapists. CBT and EMDR are both standardized trauma-focused treatments. CBT is intended to reduce the level of distress related to the traumatic event or scenario and correct dysfunctional thoughts using imaginal exposure. EMDR therapy is intended to reduce the level of distress related to a traumatic event or scenario (flash-forward) through working memory taxation.

Study burden and risks

The case series study includes three time points (i.e. before treatment, directly after treatment, and 3 months after treatment). Participants will be requested to complete online questionnaires regarding demographics, treatment expectation, disease characteristics, seizure severity, anxiety and PTSD symptom severity (30 minutes at baseline; 15 minutes at later time points). Participants will be asked to indicate their level of anxiety and seizure occurrence on a daily basis (2-3 minutes per diary registration).

The randomized controlled trial includes four time points (i.e. before treatment, directly after treatment, 3 and 6 months after treatment). Participants will be requested to complete online questionnaires regarding demographics, treatment expectation, disease characteristics, seizure severity,

anxiety, PTSD symptom severity, quality of life, personality, depression, chronic everyday stress and psychopathology (60 minutes at baseline; 30-45 minutes at later time points). During CBT and EMDR therapy, participants will be asked to wear an ECG sensor to collect measures of physiological stress (heart rate variability). Furthermore, during the study participants will be asked to indicate their level of anxiety and seizure occurrence on a daily basis (2-3 minutes per diary registration).

CBT and EMDR therapy will be provided by experienced therapists and are already part of the standard psychological treatment at SEIN. There is a minimal risk of a (temporary) increase in seizure frequency as the participants actively need to confront their most disturbing memories or scenarios. This can be a trigger for seizures for some people with epilepsy. The participants will be informed, and in case of a seizure occurring during therapy, the patient and therapist will decide whether the session can continue. If the participant feels that the sessions are too burdensome he or she can withdraw from the study at any time. The ECG sensor is wearable and miniaturised, thus minimising discomfort. In case of discomfort, the ECG sensor may be removed. Participants in the treatment conditions are expected to benefit from study participation in terms of reduced levels of anxiety and stress. We expect that their reduced anxiety and stress level will lead to a decreased seizure frequency and increased quality of life.

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

-Diagnosis of definite epilepsy
-Epilepsy-related anxiety symptoms and/ or a diagnosis of (subtreshold) posttraumatic stress disorder (PTSD)
-18 years or older

Exclusion criteria

-The presence of psychological symptoms other than anxiety or PTSD in more urgent need of treatment (e.g. suicidal intent/acts or acute psychosis)
-Not able to read/write and communicate in the Dutch language
-Currently receiving another form of psychological treatment
-Presence of psychogenic non-epileptic seizures
-Estimated IQ <80

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-03-2019
Enrollment:	85
Type:	Actual

Ethics review

Approved WMO Date:	05-10-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	28-05-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	21-09-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL64820.058.18

Study results

Date completed: 04-02-2021

Summary results
Trial ended prematurely