

EPILEPSY AND ANXIETY: TARGETING A VICIOUS CYCLE. Effectiveness of EMDR in targeting epilepsy-related anxiety, quality of life and subjective cognitive functioning

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To test the hypotheses that EMDR therapy will significantly (1) reduce anxiety in persons with epilepsy-related anxiety symptoms, from pre-treatment to post-treatment, (2) reduce seizure frequency and severity and will (3) improve quality of life...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cranial nerve disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON51770

Source

ToetsingOnline

Brief title

EPILEPSY AND ANXIETY: TARGETING A VICIOUS CYCLE.

Condition

- Cranial nerve disorders (excl neoplasms)
- Anxiety disorders and symptoms

Synonym

epilepsie anxiety

Research involving

Human

Sponsors and support

Primary sponsor: Stichting Epilepsie Instellingen Nederland

Source(s) of monetary or material Support: vanuit instelling zelf

Intervention

Keyword: anxiety, cognition, emdr, epilepsy

Outcome measures

Primary outcome

The main outcome measure is level of anxiety, which will be assessed by several questionnaires at three time points, i.e., before treatment, directly after treatment and 3 months after treatment, and self-reported anxiety based on the diary on a weekly basis.

Secondary outcome

The secondary outcome measures are quality of life, subjective cognitive complaints and seizure frequency and severity, which will be administered at three time points, i.e. before treatment, directly after treatment and 3 months after treatment, and seizure frequency in the past four weeks based on the diary on a weekly basis.

Study description

Background summary

Anxiety disorders are present in about 20-27% of people with epilepsy (PWE). The unpredictable and uncontrollable nature of epilepsy often results in anxiety symptoms, which may provoke new seizures. Psychological interventions may be beneficial to break this vicious cycle. The current study aims to investigate the efficacy of eye movement desensitization and reprocessing (EMDR) therapy in reducing epilepsy-related anxiety symptoms. Due to the adverse impact of anxiety on seizure occurrence, health-related quality life

and on cognitive complaints it is of interest to study whether EMDR therapy and the expected reduction of anxiety will also reduce seizure frequency and severity and improve quality of life and subjective cognitive functioning.

Study objective

To test the hypotheses that EMDR therapy will significantly (1) reduce anxiety in persons with epilepsy-related anxiety symptoms, from pre-treatment to post-treatment, (2) reduce seizure frequency and severity and will (3) improve quality of life and subjective cognitive functioning in persons with epilepsy-related anxiety symptoms.

Study design

A cohort study with repeated measures (before treatment, directly after treatment, and 3 months after treatment).

Intervention

EMDR therapy is a standardized psychological treatment, that will be delivered by licensed and experienced therapists during weekly sessions.

Study burden and risks

There is a minimal risk of a (temporary) increase in seizure frequency as therapy requires participants to actively confront their worst disaster fantasy. This could be a trigger for seizures for some PWE. The participants will be informed, and in case of a seizure occurring during therapy, the subject 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. PWE are expected to benefit from study participation in terms of reduced levels of anxiety. The reduced anxiety and stress level may result in decreased seizure frequency and severity, as well as improvement of quality of life and subjective cognitive functioning.

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 (ILAE)
- HADS anxiety sub score ≥ 8 at the following three time points: at referral to the psychology department, during the interview at the psychology department and just before start of the treatment.
- epilepsy-related anxiety symptoms operationalized as having a seizure-related disaster fantasy (flashforward from the EMDR protocol)
- 18 years or older

Exclusion criteria

- The presence of psychological symptoms other than anxiety 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
- Presence of neurodegenerative disorders
- Estimated IQ < 80
- Epilepsy surgery within the last year
- The use of benzodiazepines, unless subscribed as an anti-epileptic drug (AED)
- HADS anxiety sub score < 8 during one or more of the three time points: at

referral to the psychology department, during the interview at the psychology department and just before start of the treatment.

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 04-10-2022

Enrollment: 20

Type: Actual

Ethics review

Approved WMO

Date: 12-09-2022

Application type: First submission

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	NL80250.058.22