The Effectiveness of Flashforward EMDR Treatment for patients with an ICD

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The main objective is to study whether flashforward (FF) EMDR alone is effective in reducing anxiety symptoms in ICD patients.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON56774

Source
ToetsingOnline

Brief title
eFFective

Condition

- Cardiac arrhythmias
- Anxiety disorders and symptoms

Synonym
anxiety

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anxiety, Flashforward EMDR, ICD

Outcome measures

Primary outcome

To assess the disease specific anxiety levels of the participants, the patients will fill out the Cardiac Anxiety Questionnaire (CAQ). The CAQ is a self-report questionnaire consisting of 18 items, divided in three subscales (fear: 8, avoidance: 5, and attention: 5) created to measure heart-focussed anxiety. Patients rate every item on a 5-point Likert scale, ranging from 0 (never) to 4 (always). The score per subscale is calculated as the mean per subscale divided by the number of items per subscale. The total score is calculated as the mean of all items, where a higher score indicates greater heart-focussed anxiety.

Secondary outcome

• LEC-5 to obtain information about previous traumatic life events which can affect their anxiety levels and sensitivity for the EMDR treatment;

• PTSD Check-List (PLC-5) to examine PTSD symptoms;

• General Anxiety Questionnaire (GAD-7) to examine general anxiety symptoms.

• Patient Health Questionnaire (PHQ-9) to examine depression symptoms;

• EuroQol (EQ5D-5L) to examine quality of life.

Study description

Background summary

Patients with an implantable cardioverter defibrillator (ICD) are at risk of ventricular arrhythmias (VA). The ICD is a device that can treat VA by

antitachycardia pacing or ICD shocks. Since ICD shocks are painful and unpredictable, patients with an ICD can suffer from anxiety symptoms. Eye movement desensitization and reprocessing treatment (EMDR) is an effective treatment to enhance the process of traumatic events. In addition, this treatment has also shown to be able to reduce anxiety symptoms. EMDR treatment according to standard protocol starts with flashback (FB) procedure and may be followed by the flashforward (FF) procedure. The FB procedure focusses on events that happened in the past, while the FF procedure aims to reduce fear evoked by images of imagined future adverse events. So far, it is not clear whether the FB procedure is always necessary for the EMDR treatment to be effective. Moving straight towards application of the FF procedure (without first applying the FB procedure), may save treatment time and costs.

Study objective

The main objective is to study whether flashforward (FF) EMDR alone is effective in reducing anxiety symptoms in ICD patients.

Study design

This study applies a randomized controlled study design. After having signed informed consent, patients are randomly allocated to one of three groups. They fill-out the baseline (T0) questionnaires (LEC-5, PCL-5, CAQ, GAD-7, PHQ-9, EQ5D-5L) before the treatment. The FF EMDR group starts directly with two sessions of FF EMDR treatment, without FB procedure. The EMDR FB group starts with FB EMDR during the first two sessions. Within one to four weeks after the intake, the participant will have the first EMDR session. The EMDR sessions will take 90 minutes at maximum and the exact session duration will be timed. The second EMDR session will be scheduled a week after the first one. Just before the second EMDR session, the participant will fill out the CAQ (T1). After the second EMDR session, the patient receives another set with 5 questionnaires (T2; PCL-5, CAQ, GAD-7, PHQ-9, EQ5D-5L) which they will in after the second EMDR session. Three months after the T2 questionnaires, the patient receives the set with 5 questionnaires (T3; PCL-5, CAQ, GAD-7, PHQ-9, EQ5D-5L) again to measure the effects over a longer period of time. The control group will be on a waiting list for the EMDR treatment hand in the T0 questionnaires 2 weeks after their intake. One week later they will fill out the CAQ (T1) and one week after that, they will fill out the T2 questionnaires. After that, they will receive EMDR treatment (which will not be monitored for the purpose of this study).

Intervention

The two treated groups will both receive two EMDR treatment sessions. During the EMDR sessions with patients of the FB group, the focus will be on events from the past that are perceived as traumatic (flashback or FB), according the

standard EMDR protocol. During the EMDR sessions of the patients in the FF group, the focus will be on images of (feared) future events (so-called disaster fantasies), according to the flashforward procedure of the EMDR protocol.
If the patient requires more than two treatment sessions, the treatment will be continued with the same psychologist (outside the study context).

Study burden and risks

We expect that both the FB procedure and the FF procedure will benefit participants by in reducing their anxiety symptoms. Worsening of symptoms or adverse events as a result of the intervention are not expected. The duration of the waiting-list control period is relatively short and falls within the range of the average waiting time before start of treatment, so this will not impede an extra burden to patients allocated to the waiting list -control arm. Study burden consists of filling out questionnaires at three time points.

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

Participants have anxiety symptoms related to their ICD.

Exclusion criteria

Severe psychatric disorders that warrant (other)psychiatric treatment first.

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:	Recruiting
Start date (anticipated):	01-06-2024
Enrollment:	33
Type:	Actual

Ethics review

Approved WMO

Date:	23-05-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	06-01-2025
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
ClinicalTrials.gov	NCT06174051
CCMO	NL85546.078.24