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Eye movement desensitization and reprocessing treatment of terrifying voices

Submission date
31/03/2022

Recruitment status
No longer recruiting

Registration date
13/04/2022

Overall study status
Completed

Last Edited
09/10/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Auditory-verbal hallucinations (AVH, or 'hearing voices') are a common phenomenon in many psychiatric disorders. Current treatments for alleviating distress or frequencies of AVH are only moderately effective. Eye Movement Desensitization and Reprocessing (EMDR) is an evidence-based treatment for post-traumatic stress disorder (PTSD). In PTSD, EMDR decreases the emotionality and distress of memories of traumatic events. Recent studies prove that EMDR also decreases the emotionality of memories of voice-hearing. These studies suggest EMDR-treatment may also alleviate voice-hearers' distress. EMDR treatment may lead to a decrease in the negative impact of fear-inducing AVHs. EMDR treatment may also decrease other PTSD symptoms because of the strong association found between trauma and psychosis.
This study has two primary objectives. The first is to investigate whether EMDR treatment will lead to a decrease in the negative impact of fear-inducing AVH. The second objective is to investigate whether the EMDR treatment will also lead to a decrease in PTSD symptoms. As a secondary objective the researchers will explore whether the following characteristics of voice-hearing will change in the process: beliefs about voices and their origin, the amount of control the patient has over his voices, the amount of fear induced by the voices, the degree of negative content uttered by the voices, and frequency, number and loudness of voices.

Who can participate?
Mentally competent voice-hearing patients aged 18 years and older who suffer from fear-inducing AVHs that negatively impact their lives and receive outpatient treatment at Altrecht, ABC Vroege Psychose or at one of the Gebiedsteams GGZ (FACT)

What does the study involve?
Participants are randomly allocated to one of two groups: an intervention group who receive treatment as usual (TAU) and EMDR treatment, and a control group (TAU). EMDR treatment involves one or two case conceptualization sessions and eight EMDR treatment sessions. The impact of voice-hearing, PTSD symptoms and several characteristics of voice-hearing will be measured before and after treatment and at follow-up.

What are the possible benefits and risks of participating?
There is no reason to believe that EMDR treatment causes a different amount of stress than

other forms of psychological treatment for voice-hearing. Earlier research into the treatment of other symptoms has shown no negative consequences of EMDR for people with AVH; on the contrary, participants receiving EMDR treatment showed less dysregulation (poor ability to manage emotional responses) than those in the control groups. Serious adverse events occurring during this study were found to be unrelated to the study. However, should any negative consequences arise, the patient's attending mental health specialist will be informed and necessary care will be provided. Patients in the EMDR group will attend nine or ten 90-minute visits to their therapist and will be asked to fill out questionnaires three times, which will take about 90 minutes altogether. Patients in the EMDR group may experience a decrease in distress and the impact of voice-hearing as a benefit. They may also experience a decrease in PTSD symptoms (if present). When the results of the study are positive, EMDR will also be offered to patients in the control group once all data have been assessed. TAU will be continued during the study.

Where is the study run from?
Stichting Altrecht (Netherlands)

When is the study starting and how long is it expected to run for?
March 2021 to June 2025

Who is funding the study?
1. Investigator initiated and funded
2. Vereniging EMDR Nederland (Netherlands)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NL78917.041.21

Study information

Scientific Title
Eye movement desensitization and reprocessing treatment of fear-inducing auditory-verbal hallucinations

Study objectives
Eye movement desensitization and reprocessing (EMDR) treatment will lead to a decrease in the negative impact of fear-inducing auditory-verbal hallucinations (AVH) and will also lead to a decrease in comorbid post-traumatic stress disorder (PTSD) symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/12/2021, Medisch Ethische Toetsingscommissie Utrecht (METC Utrecht, Afdeling Toetsing Onderzoek, Huispostnummer D 01.343, Postbus 85500, 3508 GA Utrecht, the Netherlands; +31 (0)88 75 56 376; info@metcutrecht.nl), ref: NL78917.041.21 versie 02, METC-protocolnummer 21-678/D

Study design
Single-center interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Outpatient treatment of voice-hearing patients in a mental health care institution

Interventions
The randomisation process is performed through sealed envelopes. The intervention group will receive treatment as usual (TAU) + EMDR treatment. EMDR treatment consists of one or two case conceptualization sessions followed by eight EMDR treatment sessions with a duration of 90 minutes. The control group will receive their TAU.

Intervention Type
Other

Primary outcome(s)
1. Impact of voice-hearing measured using the 'Negative Impact' subscale of the Voices Impact Scale pre-treatment, post-treatment (1 week after the last EMDR session) and at follow up (4 weeks after the last EMDR session)
2. PTSD symptoms measured using the PTSD Checklist for the DSM-5 (PCL-5) pre-treatment, post-treatment (1 week after the last EMDR session) and at follow up (4 weeks after the last EMDR session)

Key secondary outcome(s))
1. Beliefs about voices measured using the Beliefs About Voices Questionnaire - Revised subscales at pre-, post- and follow up

2. Other voice characteristics measured with visual analogue scales and a question about the number and frequency of voice-hearing at pre-, post- and follow up

Completion date
01/06/2025

Eligibility

Key inclusion criteria
1. Patients aged 18 years and older
2. Hearing voices at least once a week
3. Fear as the predominant response to voice-hearing
4. Negative impact of voice-hearing on patient's life

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Unable to participate in structured treatment or to fill out questionnaires (due to severe problems in reality testing, self-regulation, cognition, intellect of speech)
2. Insufficient mastery of the Dutch language
3. Estimated IQ <75
4. Auditory or visual impairment
5. Severe suicidality
6. Unable to restrict substance use right before and after intervention
7. Inpatient treatment while starting study participation

Date of first enrolment
15/05/2022

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
Netherlands

Study participating centre
Stichting Altrecht
Postbus 21
Bilthoven
Netherlands
3720 AA

Sponsor information

Organisation
Utrecht University

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
Vereniging EMDR Nederland (VEN)

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes