

# Eye movement desensitization and reprocessing treatment of terrifying voices

<b>Submission date</b> 31/03/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/04/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/10/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?  
Dr S. J. M. A. Matthijssen  
s.matthijssen@altrecht.nl

## Contact information

**Type(s)**  
Principal Investigator

**Contact name**  
Dr Suzy Matthijssen

**ORCID ID**  
<http://orcid.org/0000-0002-5537-112X>

**Contact details**  
Heidelberglaan 1  
Utrecht  
Netherlands  
3584 CS  
+31 (0)30 2534700  
s.matthijssen@altrecht.nl

**Type(s)**  
Scientific

**Contact name**

Mrs Maartje van de Ven

**Contact details**

Lange Nieuwstraat 52  
Utrecht  
Netherlands  
3512 PK  
+31 (0)6 83163776  
ma.van.de.ven@altrecht.nl

**Type(s)**

Public

**Contact name**

Mrs Karina Engelbert

**Contact details**

Nieuwe Houtenseweg 12  
Utrecht  
Netherlands  
3524 SH  
+31 (0)6 22192943  
k.engelbert@altrecht.nl

**Type(s)**

Scientific

**Contact name**

Mrs T Franse

**Contact details**

Nieuwe Houtenseweg 12  
Utrecht  
Netherlands  
3524 SH  
+31-6-83114368  
t.franse@altrecht.nl

## **Additional identifiers**

**EudraCT/CTIS number**

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

## 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 measure**

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)

**Secondary outcome measures**

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

**Overall study start date**

01/03/2021

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

66

**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

**Sponsor details**

Heidelberglaan 1

Utrecht

Netherlands

3584 CS

+31 (0)30 2534700

info@uu.nl

**Sponsor type**

University/education

**Website**

<http://www.uu.nl/en>

**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

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

## Intention to publish date

01/06/2026

## 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