Virtual reality therapy for voice hearing: a randomized controlled trial

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To investigate whether VR-VOICES is more effective than regular treatment for voicehearing in patients with auditory hallucinations.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON52102

Source
ToetsingOnline

Brief title
VR-VOICES

Condition

- Psychiatric disorders NEC

Synonym
auditory verbal hallucinations, Voicehearing

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Auditory hallucinations, Psychological intervention, Virtual reality, Voice-hearing

Outcome measures

Primary outcome

Voices severity (frequency and distress): the total score on the auditory hallucinations scale of the Psychotic Symptoms Rating Scales (PSYRATS interview).

Secondary outcome

Auditory hallucinations:

1. Experience sampling method (ESM) of AVH, distress and anxiety measured in the flow of daily life. ESM is a structured diary method for reporting momentary experiences 18. Individuals complete short questionnaires on their mobile device, by pressing a link in a sms. Participants will complete ESM 8x daily for 7 days, completion takes ±1 minute.

2. Voice frequency, voice distress, delusions (subscales of the primary outcome PSYRATS)

3. Beliefs about voice power, voice intent and responding styles (Beliefs about Voices Questionnaire-Revised, BAVQ-R)

4. Social comparison with voices (Social Comparison Rating Scale To Voices, SCRS)

5. Impact of voice-hearing (Stemmen Impact Schaal, SIS)

6. Voices acceptance and action scale (VAAS)

Clinical symptoms:

1. Depressive symptoms (Inventory of Depressive Symptomatology, IDS)

2. Paranoid ideation (Revised Green Paranoid Thoughts Scale, R-GPTS)

3. Self-esteem (Self Esteem Rating Scale, SERS)

Care use, costs and quality of life:

1. Quality of life (EuroQol, EQ-5D-5L, Sheehan Disability Scale, SDS)

2. Health care costs and costs production losses (TiC-P)

3. Self-efficacy/empowerment (Mental Health Confidence Scale, MHCS)

VR-VOICE group specific measurements:

1. Working Alliance Inventory, both for patient and therapist, completed at posttreatment.

2. Presence in 2 sessions (Igroup Presence Questionnaire, IPQ)

3. Experience of fit of the voice and avatar to the actual voice (two single items on a scale from 1-100), session duration, VR duration per session, goals, protocol deviations, notes and whether technical issues occurred

• Subsample: After the VR-VOICES intervention, in-depth interviews will be performed to collect the experiences of patients with VR-VOICES. This will be done in a subsample of participants (n=20)

Study description

Background summary

Auditory verbal hallucinations (AVH) - hearing voices that others cannot hear - are common in mental illnesses. For many people AVH are distressing, disabling

and persistent, despite medication. Current psychological interventions show low to medium effects. Preliminary studies suggest that an innovative empowering psychological therapy using computer simulations representing the AVH (avatars) can be effective for reducing AVH distress and frequency. Virtual reality (VR) has a potential to improve this treatment.

Study objective

To investigate whether VR-VOICES is more effective than regular treatment for voicehearing in patients with auditory hallucinations.

Study design

Single-blind randomized controlled intervention trial (RCT).

Intervention

• VR-VOICES intervention: 10-12 sessions (this includes the 2 booster session) of 45-60 minutes of individual VR assisted therapy in addition to treatment as usual (TAU).
• Control: TAU as described in the current Dutch guidelines.

Study burden and risks

The participating patients are expected to benefit from both the VR-VOICES intervention and TAU. Concerning VR-VOICES, exposure to the avatar's voice is expected to be distressing, especially in the first two weeks. However, the exposure is provided in a controlled fashion and through the guidance of the therapist, and the exposure can be stopped at any time instantly by the therapist or participant. Previous RCT and pilot studies reported no SAEs to be attributable to the therapy (n=121 have been treated with the therapy over these three trials). Furthermore, VR which is a rapidly expanding field, has been found safe to use for multiple disorders.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

• DSM-5 diagnosis of a psychiatric disorder
• Distressing AVH for minimally 3 months.
• Age 16 years or older

Exclusion criteria

• Insufficient command of the Dutch language
• Unable to provide informed consent
• Primary diagnosis of a substance use disorder, or organic brain disease (such as dementia)
• A degree of substance abuse that hinders treatment adherence
• Auditory verbal hallucinations in a language not spoken by therapists
• Patients cannot receive CBT specifically focussed at gaining empowerment over voices.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-10-2022
Enrollment:	112
Type:	Actual

Ethics review

Approved WMO Date:	07-10-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-04-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-01-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-02-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	29-08-2024

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL78885.042.22