An explorative and experimental study to assess the feasibility, acceptability and effectiveness of four imagery intervention techniques in the treatment of auditory vocal hallucinations

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

Summary

ID

NL-OMON53589

Source
ToetsingOnline

Brief title
Imagery interventions for auditory vocal hallucinations

Condition

- Psychiatric disorders NEC

Synonym
Auditory vocal hallucinaties, hearing voices

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Eindhoven (Eindhoven)
Source(s) of monetary or material Support: GGzE

Intervention

Keyword: Auditory vocal hallucinations, Imagery interventions, Mental imagery, Psychosis

Outcome measures

Primary outcome

The primary outcome variables are the level of auditory vocal hallucinations, imagery characteristics (imagery frequency, imagery appraisals and imagery quality) measured three times a day using a diary method, and feasibility and acceptability measures (adverse (side) effects, drop-out rates and qualitative review of therapy).

Secondary outcome

The secondary outcomes are the level delusions, visual hallucinations and social and occupational functioning measured three times a day using a diary method.

Study description

Background summary

Auditory vocal hallucinations are the most common hallucinations of psychosis (American Psychiatric Association, 2013; Sommer et al., 2012) and do also often occur in in patients with various other psychiatric disorders, such as Post-Traumatic Stress Disorder (PTSD), anxiety disorders, mood disorders, eating disorders or personality disorders (Laroi et al., 2012; van Os & Reininghaus, 2016; Waters et al., 2018). It remains open to debate whether theories about auditory vocal hallucinations are sufficient enough to explain the full spectrum of psychosis, since effects of both pharmacological (Carpenter & Davis, 2012) and psychological (Janssen et al., 2021; van der

Gaag et al., 2014; Wykes et al., 2008) therapies for auditory vocal hallucinations are in the small to modest range. The missing link and a potential target for treatment might be the transdiagnostic phenomenon mental imagery, as as few studies showed that patients with psychosis experience intrusive images associated with their psychotic symptoms (Morrison et al., 2002; Schulze et al., 2013). In addition, psychological interventions targeting mental imagery in several other mental disorders with overlapping features with psychosis has yielded promising results (Ehlers et al., 2005; Hales et al., 2018; Holmes et al., 2016; Wild & Clark, 2011). Also, few experimental studies investigating the effects of a few imagery interventions in addition to cognitive behavioral therapy (CBT) for patients with psychosis showed promising results (Ison et al., 2014; Morrison, 2004; Serruya & Grant, 2009). However, the working mechanism behind these interventions is not fully understood. Moreover, there is no specific imagery enhanced CBT protocol for working with auditory vocal hallucinations. Indeed, it is not known which imagery intervention techniques are feasible for patients with hallucinations. The aim of the current study is to assess the acceptability and feasibility of four imagery interventions for auditory vocal hallucinations and to assess effects of these interventions on the level of auditory vocal hallucinations and mental imagery.

Study objective

The main objective of this study is to assess the feasibility, acceptability, and effectiveness of four imagery intervention techniques adapted from the protocol of Holmes (2019) for auditory vocal hallucinations. We are primarily interested in whether these imagery intervention techniques would be associated with a decrease in auditory vocal hallucinations and imagery symptoms. Also, we are interested in whether these imagery intervention techniques would be a feasible and acceptable intervention for patients with a disorder in the transdiagnostic psychosis and suffering from auditory vocal hallucinations. Secondly, we aim to assess the effects on the level of delusions, visual hallucinations and social and occupational functioning. Lastly, we aim to explore the working mechanisms of imagery, affective symptomatology, and auditory vocal hallucinations by three times daily measuring these symptoms for a period of seven weeks.

Study design

The present research proposal concerns four single case series A-B-A within subject designs. Assessments consists of clinical questionnaires and three-time daily questions about hallucinations (both auditory and visual), delusions, imagery and affective symptoms (anxiety and depression).

Intervention

This protocol consists of four different studies assessing four imagery intervention techniques (metacognitive imagery intervention, imagery rescripting, promoting positive imagery and competing imagery task).

Study burden and risks

Risks for patients participating in this study are minimal. Similar interventions have been successfully tested in feasibility trials for patients with psychosis suffering from delusions and auditory vocal hallucinations. The results of these studies suggests that these interventions are well tolerated and received by patients. All patients, during the baseline period, during the treatment phase and during follow-up, have regular appointments with their psychiatrists or general nurse practitioner to monitor medication use, mental and daily functioning. Also, risks for patients with suicidal related auditory vocal hallucinations are minimal since the urge to act on suicidal thought or imperative auditory vocal hallucinations does not increase after talking about these thoughts. On the contrary, it seems to have a protective effect (Dazzi et al., 2014). This is the same for the use of imagery interventions in the treatment of suicidal ideations (Rahnama et al., 2013). Psychological therapy for psychosis belongs to standard care. The extra burden for participants is the daily self-monitoring, that requires participants to complete a questionnaire (5-10 min) at three at equidistant time points with a 4-hour interval in between for 49 consecutive days, the first assessment in which participants sign the informed consent and a researcher administer a clinical interview (+/- 60 minutes) and the self-report questionnaires at T0-T1-T2 (25-35 minutes).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Age 16-65 • Experiencing subclinical or clinical psychotic auditory vocal hallucinations as confirmed by a clinician and as indicated by an intensity score of 4 or more on subscale 1.3 (perceptual abnormalities) of the Comprehensive Assessment of At Risk Mental States (CAARMS; Yung et al., 2005) or as indicated by a score of 3 or more on item P3 (hallucinatory behavior) of the Positive and Negative Syndrome Scale (PANSS; Kay, Fiszbein, & Opler, 1987). • A DSM-5 (APA, 2013) diagnosis in the psychosis spectrum (codes: DSM-5 codes: 297.1; 298.8; 295.40; 295.90; 295.70; 298.8; 298.9) or defined as Ultra High Risk/At Risk Mental State (ARMS or UHR) according to the CAARMS estimated by a clinician.

Exclusion criteria

• Any current or previous neurological disorder or organic brain disease. • Acute confusional state or delirium not caused by the psychotic disorder. • Unwillingness to participate • IQ < 70 estimated by clinician. • Current severe substance or alcohol misuse impacting treatment (clinicians assessment).

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	07-04-2022
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	14-02-2022
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
Other	ClinicalTrials.gov not finalised yet
CCMO	NL79610.068.21