Altered brain dynamics of self-voice perception in voice hearers

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Schizophrenia and other psychotic disorders
Study type	Observational non invasive

Summary

ID

NL-OMON52913

Source
ToetsingOnline

Brief title
Altered brain dynamics of self-voice perception

Condition

- Schizophrenia and other psychotic disorders

Synonym
Psychosis

Research involving
Human

Sponsors and support

Primary sponsor: University of Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Psychotic Disorders, Schizophrenia, Schizophrenia Spectrum and Other Psychotic Disorders

Outcome measures

Primary outcome

The primary effect of interest/study parameter is N100 suppression effect for different types of auditory stimuli obtained during the two EEG experiments, and HP based on the scores of Launay-Slade Hallucination Scale (LSHS). N100 suppression effect will be analyzed as a function of HP scores to examine alterations in sensory feedback and attentional processes associated with voice hearing.

Secondary outcome

In accordance with our secondary objectives, secondary study measures are

a) EEG measures (e.g., P200, pre-stimulus alpha power) for self- and externally generated tones vs. neutral self-voice (Experiment. 1), and neutral changing to emotional self-voice in five steps (Experiment.2) using a auditory-motor task

b) Resting state EEG measures

c) Neuroimaging measures

d) Clinical and psychometric variables for the group assignment (voice hearers vs. controls), stratification of the voice hearer group for further exploratory analysis (with vs. without psychiatric diagnosis), as covariates (IQ), listed under *questionnaires* in the research protocol

Study description

Background summary

Altered sensory feedback and source misattribution of self-generated speech may lead to auditory verbal hallucinations (AVH) in non-clinical voice hearers as well as psychotic patients. Unlike non-clinical voice hearers, psychotic patients often report hearing derogatory voices, accentuating their attentional bias towards negatively valenced emotions and salience (threat) misattribution. However, it remains unclear whether an interplay of dysfunctional attentional processes/salience misattribution and altered sensory feedback leads to psychotic AVH. This study aims at investigating this interplay in voice hearers and, therefore, constitutes a critical advancement in terms of the understanding of the neuropsychology of AVH.

Study objective

This study will rely on a well-replicated auditory-motor task combined with EEG in two separate experiments (Experiment. 1: speech manipulation and Experiment. 2: emotion and uncertainty manipulations) to elucidate how misattribution of simple (tones) and complex auditory stimuli (neutral changing to emotional self-voices) results from neural changes in sensory feedback and/or attentional processes in voice hearers as a function of hallucination proneness (HP). In addition, sophisticated MRI will be used to examine the changes in connectivity among the underlying brain regions associated with these processes as a function of HP.

Study design

This multi-modal study involves four testing sessions. Session 1: Screening (neuropsychological assessments and interviews); Session 2: Voice recordings (to be used during session 3); Session 3: EEG (2 separate experiments); Session 4 (optional): Neuroimaging. This study does not involve any form of clinical intervention.

Study burden and risks

A total of four sessions are planned which have been designed to be as brief as possible in order to minimize the burden of the participants. The sessions will be scheduled according to the participants* preferences and with a rest period of minimum one week in between. During the sessions, frequent breaks are offered. All measures and assessments included in this study are non-invasive, meaning that potential risks are ruled out. Participants will be approached in their preferred language (Dutch or English) in order to ensure that they i) fully comprehend the extent of the study and ii) feel as comfortable as

possible during the testing sessions. Please note that there are no medical benefits for participation in the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a participant must meet all of the following criteria:
General:
• Age range: 16-65 years;
• Written informed consent;
• MRI compatible (optional)
o No metallic implants in the body (e.g., metal braces, metallic teeth filling, pacemaker etc.);

o No body tattoos with metallic ink (e.g., colored tattoos may contain metallic ink);
o No claustrophobia.

Group 1: Individuals recruited from general population who do not hear voices
This group includes individuals recruited from the general population who vary from low to high HP based on LSHS scores (university students, participant panels, public advertisement).
o No reported history or current diagnosis of any neurological disorder;

Group 2: Individuals recruited from general population who hear voices
o score on item 8 or 10 of LSHS greater than 0;
o score on item 9 should be 0, meaning these individuals are not troubled by the voices;

o Item 8: *I often hear a voice speaking my thoughts aloud*;
o Item 9: *I have been troubled by hearing voices in my head*;
o Item 10: *In the past, I have had the experience of hearing a person*s voice and then found that no one was there;

o no reported history or past or current diagnosis presence of any neurological disorder.

Group 3: Clinical voice-hearers.
This group includes individuals with or without formal diagnosis of psychotic disorder who seek help for their mental health such as at high-risk for psychosis individuals, psychotic patients with past/present AVH experience.
o scores on item 9 and 8 and/or 10 of LSHS greater than 0, meaning not only do they hear voices but are also troubled by them;

Please note that the categorization of participants is merely for the recruitment purposes and statistical analyses will be based on the continuum perspective. Duration and dosage of any antipsychotic medication will be recorded and used as covariates in the analyses.

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in this study:
o Any previous neurosurgery or neurological disorder, including epilepsy;
o Refusing to have EEG performed;
o Inability to fully comprehend the purpose of the study or to make a rational decision whether or not to participate;

If voice hearing is caused exclusively by substance abuse (drug or alcohol addiction) or a neurological condition such as tumor or lesions etc.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2021
Enrollment:	231
Type:	Actual

Ethics review

Approved WMO Date:	12-11-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-11-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-07-2022

Application type:	Amendment
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

ID: 23432
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL72992.068.20
Other	NL9508
OMON	NL-OMON23432