Onderzoek naar ‘dingen zien die er niet zijn’ bij psychotische aandoeningen (deel 2)

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24629

Source
Nationaal Trial Register

Brief title
INZICHT part 2

Health condition

visual hallucinations, psychotic disorders, fMRI

Sponsors and support

Primary sponsor: University Medical Center Groningen (UMCG)
Source(s) of monetary or material Support: University Medical Center Groningen (UMCG)

Intervention

Outcome measures

Primary outcome

fMRI study 1: cortical activation, reflected by the Blood-Oxygen-Level-Dependent (BOLD)-level, while an extended version of the Image Recognition Movies test is performed. In total,

50 pictures will be gradually pop out of white noise. During a movie, with random intervals, a central fixation square changes color. Participants are asked to push a button with their right middle finger on a response box, to keep attention constant.

fMRI study 2: resting state scans: also cortical activation, reflected by the Blood-Oxygen-Level-Dependent (BOLD)-level.

fMRI study 3: cortical activation, reflected by the Blood-Oxygen-Level-Dependent (BOLD)-level, during population receptive field mapping.
During this retinotopic mapping, participants are presented with a bar and wedges with a checkerboard pattern which moves across the screen.

fMRI study 4: resting state scans while pushing buttons for VH: also cortical activation, reflected by the Blood-Oxygen-Level-Dependent (BOLD)-level.

Secondary outcome

fMRI study 1: motor response for pushing buttons on recognition and when the central fixation square changes color

fMRI study 3: motor responses, as during this test too, a central fixation dot changes color with random intervals. Participants are asked to push a button on a response box, to keep attention constant.

fMRI study 4: motor responses, as during this scan patients push a button when they start experiencing VH, and push an other button when the VH stops.

Study description

Background summary

See NTR5103 for the first part of this study and the background for this study. The main goal of the INZICHT-studie, part 1 and 2 together, is to gain insight in to the pathofysiology of visual hallucinations in psychotic disorders. INZICHT part 2 includes multiple fMRI studies, comparing 3 groups of patients: patients with a psychotic disorder with visual hallucinations; patients with a psychotic disorder without visual hallucinations, and healthy controls.

The objectives of these studies are

1) to search for a bottom-up (or top-down) disorder by assessing neuronal circuitry and cerebral activation patterns both before and during object recognition tasks (Image Recognition Movies);

2) to explore what brain mechanisms predispose patients with a psychotic disorder to

generate visual hallucinations, using resting-state fMRI scans;

3) to explore detailed differences in the visual system and in particular bottom-up processing in psychotic patients with visual hallucinations (with retinotopic mapping fMRI-scans is;

4) to explore the direct neuronal correlates of VH in psychotic disorders (resting-state fMRI-scan with pushing buttons for the beginning and end of VH).

Study objective

The objectives of this second part of the study, involving fMRI:

1) to search for a bottom-up (or top-down) disorder by assessing neuronal circuitry and cerebral activation patterns both before and during object recognition tasks (IRM), using fMRI. We may hypothesize that fMRI will show the delay in image recognition (like in Parkinson's disease), reflected in reduced bottom-up visual activation in occipital-temporal areas.

2) to explore what brain mechanisms predispose patients with a psychotic disorder to generate visual hallucinations, using resting-state fMRI scans. We may find aberrant connectivity between the visual cortex, frontal regions and medial temporal lobe structures (top-down disorder). We hypothesize to find decreased connectivity between visual-related regions (bottom-up disorder). By exploring attentional networks in psychotic disorders, we may find changes in activity of the DMN (as in visual hallucinations in brief psychotic disorder) or in the DAN (as in visual hallucinations in PD);

3) to explore detailed differences in the visual system and in particular bottom-up processing in psychotic patients with visual hallucinations (with population receptive field mapping). We hypothesize that patients with visual hallucinations show smaller population receptive fields and connective fields than patients without visual hallucinations.

4) to explore the direct neuronal correlates of VH in psychotic disorders (resting-state fMRI-scan with pushing buttons for the beginning and end of VH). We hypothesize to find brain activity related to the VH in in the visual cortex and medial temporal lobe structures, suggesting retrieval of visual images for memory

Study design

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Intervention

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Contacts

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Eligibility criteria

Inclusion criteria

Patients must fulfill the following criteria:

1) meeting DSM-IV criteria for schizophrenia, schizophreniform disorder, schizoaffective disorder or psychotic disorder NOS;

2) 2) in case of psychiatric comorbidity: the psychotic disorder is predominating. In case of visual hallucinations: they are related to the primary psychotic disorder. Both are confirmed by their own psychiatrist.

3) age between 18-55;

4) speaking Dutch fluently;

5) being able to give informed consent.

Healthy controls must fulfill the following criteria:

1) age between 18-55;

2) speaking Dutch fluently;

3) being able to give informed consent.

Exclusion criteria

Exclusion criteria are:

1) other psychiatric disorders than above mentioned schizophrenia spectrum disorders that presumably affect our data:

Mental retardation, amnesia, other cognitive disorders: if MMSE <26

Delirium

Dementia

Current substance dependence (except for nicotine and caffeine)

Dissociative disorders

Borderline personality disorder

2) the presence of accompanying neurological disorders that supposedly influence our data:

Dementia

Degenerative, demyelinating or inflammatory diseases of the central nervous system

Other non-congenital anatomical cerebral abnormalities such as tumors and infarcts

Epilepsy

Congenital brain injury

Brain surgery

Current (mild) traumatic brain injury or a medical history of more severe traumatic brain injury

3) visual acuity less than 50 percent (Snellen chart);

4) visual field defects (Donders technique);

5) cognitive impairment, which is assessed by Mini-Mental State Examination. The cut-off point is <26.

Exclusion criteria for part 2 (fMRI):

6) presence of implantable devices (electronically, magnetically or mechanically activated, for example implanted insuline pumps, cardiac pacemakers, cardioverter-defibrillators, metallic prosthetic heart valves, cochlear implants);

7) medical disorders because of which patients are unable to lie flat for about 30 minutes, for example poorly controlled heart failure and poorly controlled or severe respiratory disease;

8) ferromagnetic clips;

9) intraocular metallic particles;

10) pregnancy;

11) claustrophobia;

12) colored tattoos;

13) coils (exception: Mirena);

14) weighing more than 140 kg;

Furthermore, healthy controls are excluded if they ever have had a psychotic episode; if they have visual hallucinations; or if they have a first degree family member who had a psychotic episode or a psychotic disorder.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-09-2015

Enrollment:	51
Type:	Anticipated

Ethics review

Positive opinion
Date: 29-11-2017
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45154
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6685
NTR-old	NTR6855
CCMO	NL39518.042.12
OMON	NL-OMON45154

Study results