

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

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24629

Bron

Nationaal Trial Register

Verkorte titel

INZICHT part 2

Aandoening

visual hallucinations, psychotic disorders, fMRI

Ondersteuning

Primaire sponsor: University Medical Center Groningen (UMCG)

Overige ondersteuning: University Medical Center Groningen (UMCG)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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 pathophysiology 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).

Doel van het onderzoek

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 the visual cortex and medial temporal lobe structures, suggesting retrieval of visual images for memory

Onderzoeksopzet

-

Onderzoeksproduct en/of interventie

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Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	08-09-2015
Aantal proefpersonen:	51
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 29-11-2017

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45154

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten