An fMRI investigation of the neural substrate of cognitive insight in non-clinical subjects

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON43071

Source
ToetsingOnline

Brief title
Cognitive insight in non-clinical subjects

Condition

- Other condition

Synonym
it involves healthy subjects., This study is not aimed at a certain disorder

Health condition

zelf-reflectie en open staan voor mening van anderen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cognitive insight, Mindfulness, MRI, Processing of self-related social feedback

Outcome measures

Primary outcome

The main study parameters are brain activation and/or connectivity during tasks, and brain (functional and structural) connectivity during resting state, in relation to cognitive insight. Blood-oxygen-level-dependent (BOLD) signal will be measured during the performance of two different tasks and at rest using fMRI. In addition, a special kind of diffusion-weighted imaging (DWI) called diffusion tensor imaging (DTI) will be used to examine the relationship between the integrity of white matter tracts and cognitive insight, while structural MRI scans will be used to examine grey matter volume in relationship to cognitive insight.

Secondary outcome

Secondary study parameters are cognitive test scores on the Sustained Attention to Response Task (sustained attention, inhibition and meta-awareness).

Study description

Background summary

Insight into illness is impaired in 50-80% of patients with schizophrenia and has been associated with treatment non-adherence and poorer prognosis in general. Several theories have been proposed to explain the etiology of

impaired insight and we propose a multifactorial etiology combining different theories, hypothesizing that impaired cognitive insight has neurobiological, neuropsychological, and psychological aspects. A distinction between cognitive and clinical insight is made. Cognitive insight is the ability to reflect upon one*s own thoughts and behaviors and to be open to corrective feedback from others, while clinical insight involves (1) awareness of being ill, (2) attribution of symptoms to the illness and (3) realizing need for treatment. Multiple studies have examined the neural basis of clinical insight in psychosis. Measures of clinical insight do not address the impaired ability to evaluate aberrant experiences and the openness to corrective feedback from others, even though these cognitive deficiencies may contribute to impaired clinical insight. Patients may therefore sometimes appear to have good clinical insight, while this may just reflect superficial beliefs or repetition of explanations from psychiatrists. Cognitive insight can also be measured in people without a mental disorder (i.e. non-clinical subjects). Learning more about the neural substrate of cognitive insight in non-clinical subjects could improve our understanding of impaired insight in psychotic disorders and could also be of value for treatment, as these aberrant cognitive thinking styles can be used as targets for intervention.

Study objective

To investigate the neural substrate of cognitive insight in non-clinical subjects.

In this project we will test several hypotheses: (1) individuals with lower levels of cognitive insight will be less able to use feedback to correct self-evaluation, and will show less brain activation and/or connectivity of relevant brain areas during processing of self-related feedback compared to individuals with higher levels of cognitive insight, (2) individuals with lower levels of cognitive insight will show less brain activation and/or connectivity of relevant brain areas (associated with attentional regulation: re-shifting and sustaining attention) during a brief mindfulness induction, (3) individuals with lower levels of cognitive insight will show less functional and structural connectivity of the default mode network (DMN) during resting state, and (4) individuals with lower levels of cognitive insight will have more problems with sustained attention, inhibition and meta-awarenesss.

Study design

This observational study will combine fMRI and behavioral measurements. Participants will be recruited from different places in Groningen via advertisements (for example at the RUG, UMCG, Hanze University of Applied Sciences, and different institutes that offer courses on meditation, yoga or mindfulness, etc). We will include both participants with and without mindfulness experience. 200 participants will be screened of which 60

participants will be included based on their score on the self-reflection (SR) subscale of the Beck Cognitive Insight Scale (BCIS): 20 individuals with low (25% lowest scores), 20 with average (middle 50%) and 20 with high (25% highest scores) cognitive insight. They will participate in two experimental sessions that involve filling in of several questionnaires (22 minutes), a computer task (30 minutes), a monopoly game as preparation for one of the fMRI-tasks (45 minutes), rating of their own and other*s traits (max 30 minutes), scanning (78 minutes) and cognitive tests (15 minutes). The scanning session will consist of the following: two different fMRI tasks, a resting state fMRI scan, a diffusion weighted image (DWI) and a structural MRI-scan.

Study burden and risks

The participant's burden consists of online screening questionnaires (duration: 25 min), a screening interview (duration: 15 min) and two experimental sessions (1st session of 135 minutes; 2nd session of 145 minutes). Participants will be selected based on their response on four questionnaires and the interview during the screening moment. During the screening moment it is ensured that all requirements are met. The first experimental session will take approximately 2 hours and 15 minutes at most including a break. During the first session, participants will complete several questionnaires on a PC (22 minutes), complete a computer task (30 minutes), complete a cognitive test (5 min), play a game in preparation of one of the fMRI tasks (45 minutes), rate three other participants on trait characteristics (18 minutes), and will be shown the dummy MRI scanner. The second experimental session will take place the day after and will last approximately 2 hours and 25 minutes including a break. During this session, participants will be scanned (78 minutes), they have to rate themselves and one other participant (12 minutes), and a cognitive test will be conducted (10 minutes). Before the scanning session the participant will be required to fill and sign a safety-specific questionnaire. The participants will perform two computer-based paradigms during scanning, with a duration of approximately 48 minutes (social feedback task: 36 minutes; mindfulness induction: 12 minutes). We do not expect these paradigms to be problematic in the current group of participants.

To undergo an MRI scan involves: exposure to loud noise (addressed with ear protection, by means of both ear plugs and headphones), a moderate amount of physical restraint (the head is inside an MRI coil; the feeling is similar to wearing a motorbike helmet), as well as to a strong constant magnetic field (3Tesla), and small variable electromagnetic fields. Functional MRI is an eminently safe technique; there are no risks that have been associated with the acquisition of fMRI data per se. Participants will be exposed to a magnetic field of 3 Tesla and rapidly alternating gradients and radio frequency fields. These field and gradients' changes are routinely used in fMRI and MRI research. The strong magnetic fields used by fMRI can dislocate ferromagnetic particles inside the brain and the eyes, interfere with the functioning of electronic devices implanted inside a person's body (pacemakers, insulin pumps, etc.), as

well as induce heating in artificially metal-rich regions (red tattoos, metallic supports to previously fractured bones, prosthetic implants). In order to avoid the risks involved with such possible conditions, participants will be required to complete a questionnaire and only if none of the exclusion criteria are met the participant will be allowed to participate in our experiment.

The environmental conditions of being inside an MR scanner and of being partially restrained can induce claustrophobic feelings. Three steps will be taken to reduce this risk: 1) the participant will be explicitly asked about being claustrophobic, 2) the participant will experience a training moment in a dummy scanner and 3) prior to the beginning of the actual experiment, and during pauses between scans, participant will be asked about their wellbeing. Additionally, they will receive an alarm trigger that they will be able to use at any moment to interrupt the scanning. Finally, an experimenter will be in close proximity of the participant during the session, which will allow a close monitoring of the participant*s wellbeing.

The study is not intended to benefit the participants directly. Participants will receive compensation for their contribution.

Contacts

Public
Selecteer

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Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Being right-handed (based on Edinburgh Handedness inventory questionnaire)
* Age 18-65
* Normal (or corrected to normal) vision
* fMRI-compatible
* Capable of giving informed consent
* Fluent in written and spoken Dutch

Exclusion criteria

* Not matching any of the inclusion criteria
* Matching any criterion in the fMRI exclusion list, including, but not limited to, claustrophobia, infarctions, epilepsy or family history of epilepsy, presence of metal inside the body, presence of electric/electronic devices inside the body (pacemakers, etc.), presence of intracardial lines, (suspicion of) pregnancy, tattoo(s) that contain red pigment, any risk of having metal particles in the eyes
* Non-removable dentures
* Use of medication that can influence task performance. For example, medication that target blood pressure or heart rate (e.g. beta-blockers). Also, use of antidepressants, anxiolytic, and anti-epileptic drugs
* Use of drugs such as cannabis, XTC or other recreational drugs
* Presence or history of neurological, psychiatric or substance dependence disorder
* Previous mindfulness or other formal meditation experience

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-12-2016
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	22-11-2016
Application type:	First submission
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	NL59185.042.16