The neural basis of congitive-emotional processing in people with an at-risk mental state for developing psychosis

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

Summary

ID

NL-OMON33062

Source
ToetsingOnline

Brief title
The neural basis of at-risk menatl state for psychosis

Condition

- Schizophrenia and other psychotic disorders

Synonym
psychosis, schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ESF-NWO

Intervention

Keyword: cognitive-emotional processing, psychosis, schizophrenia

Outcome measures

Primary outcome

In this study brain activation during cognitieve processing will be investigated in two separate sessions, separated by 8 months. Questionnaire scores will be linked to brain activation. Through diagnostic interviews and symptom evalutions 2 years after the first fMRI scan will be conducted, to evaluate whether fMRI activation was predictive of the clinical state 2 years later.

Secondary outcome

n.a.

Study description

Background summary

Schizophrenia affectts individuals in their personal, social and occupational development and functioning. Besides cognitive deficits it is characterized by deficits in emotional processing and regulation. There is an increasing interest in the role of social cognitive processes in schizophrenia. Deficits in social function are present throughout the course of the disorder and are even present before onset of psychosis and have been shown to contribute to the rate of relapse. A crucual finding is that performance on social cognition tasks predicts social functioning, and that this assocaion cannot be accounted for by general cognitive deficits. There is also neuroantomical evidence of abormalities in brain circuits subserving social cognition in schizophrenia (at-risk mental state for schizoprhenia, ARMS). Such research can uncover the mechanisms involved in tranisition to psychosis and schizophrenia. This might ultimately enable the development of prevention strategies, which would have very significant implications in terms of mental health care.

Study objective

The objective of this study is threefold. First, to investigate neural correlates of cognitive-emotional processing in an ARMS sample, i.e. help-seeking young people with an at-risk mental state (this will be addressed in the base-line measurement). Second, we will investigate putative changes after 8 months. This will give us information regarding the neural correlates of symptom changes over time. In addition, it wil allow us to compare the effects of interventions that have been applied, be it treatment as usual or cognitive therapy (the intervention is not part of the present study, but concerns an already ongoing project at the psychiatric institute). Finally, we want to conduct diagnostic interviews and symptom evaluations 2 years after the first fMRI-scan, to evalute whether fMRI activation is predicitive of the clinical state 2 years later.

Study design

Using functional magnetic resonance imaging (fMRI) we will investigate the neural basis of 3 cognitive processes that are highly relevant; reality monitoring, emotion regulation and self-reflection. After 8 months subjects will be scanned a second time, using the same tasks. Finally, we want to conduct diagnostic interviews and symptom evaluations 2 years after the first scan, to evaluate whether fMRI activation is predictive of the clinical state 2 years later.

Study burden and risks

Participants will be exposed to a 3 T magnetic field. No side effects have been described so far. On rare occasions, a peripheral nerve (abdomen) is stimulated by the changing magnetic gradients, this will cause an itchy feeling, but is not harmful.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- healthy individuals, male and female with IQ in the normal range and with normal or corrected to normal vision.
- between 18 and 45 years old

Exclusion criteria

- neurological problems (incl. epilepsy)
- use of drugs that may influence the task
- contra indications for fMRI will lead to exclusion, fMRI-exclusion criteria:
- MR incompatible implants in the body (such as ear prothesis or other metal implants)
- any risk of having metal particles in the eye
- tattoos containing red pigments
- (suspected) pregnancy
- claustrophobia
- the refusal to be informed of structural brain abornamilities that could be detected during the experiment.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-12-2009
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	20-10-2009
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

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	NL28576.097.09