Insight in affective versus non-affective psychosis: an fMRI study

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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-OMON32774

Source
ToetsingOnline

Brief title
Insight in 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: NWO

Intervention

Keyword: emotion regulation, Insight, psychosis, self-esteem, self-reflection, social reward

Outcome measures

Primary outcome

Main study parameters are signal change in bold responses in self-evaluation

and emotion regulation processes in relation to illness insight.

Secondary outcome

Secondary study parameters are behavioural differences between groups in terms

of percentages correct and reaction times regarding the experimental tasks.

Study description

Background summary

Lack of insight (unawareness of illness) is a common and clinically relevant feature of psychosis. The cognitive and neural bases of insight in psychosis remain unclear, however, rendering it a scientific mystery. This project will test the hypothesis that lack of insight in psychotic patients is associated with reduced activation of brain circuits subserving self-evaluation and emotion regulation. In short, it is presumed that implicit experiential self-processing is biased towards maintaining a positive self-image (which excludes mental illness). To obtain insight in psychosis, rational, explicit self-processing must overrule this automatic response. This will only occur in the face of sufficient cognitive capacity and motivation. However, a large number of psychotic patients lack both. Furthermore, a comparison will be made between patients suffering from affective psychosis versus non-affective psychosis since in affective psychosis lack of insight seems to be a state related, whereas in non-affective psychosis lack of insight is thought to be a trait characteristic. These hypotheses will be tested using methods from cognitive social psychology and functional neuroscience applying functional magnetic resonance imaging (fMRI). This would be an innovative research that elucidates the cognitive and neural bases of self-processing in relation to poor insight (awareness of illness) in psychosis.

Study objective

The aim of the proposed research is to test the hypothesis that lack of insight in psychosis is associated with reduced activation of brain circuits subserving self-evaluation and emotion regulation and that this relationship is also dependent on whether the nature of the psychosis is affective or non-affective.

Study design

In this study a total of 100 subjects will participate of which 80 subjects will be patients with a diagnosis of a psychotic disorder. Subjects will be asked to fill in a total of 7 questionnaires, 5 task outside of the fMRI scanner, and 3 tasks while lying in the fMRI scanner. Furthermore, 4 interviews will be conducted in patients, the Young Mania Rating Scale, the Positive And Negative Symptom Scale, the Schedules for Clinical Assessment in Neuropsychiatry and the Scale to Assess Insight - Expanded.

Study burden and risks

Subjects will be exposed to a magnetic field of 3 Tesla and rapidly alternating magnet gradients and radio frequency fields. This field strength is used on a routinely basis in fMRI and MRI research. So far, no side effects have been described. On rare occasions, a peripheral nerve (abdomen) is stimulated by the changing magnet gradients. This will cause an itching feeling, but it is not harmful.
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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

A total of 40 Patients must have a diagnosis within the schizophrenia spectrum, either schizophrenia or schizophreniform disorder. A total of 40 patients must have a diagnosis within the mood disorders, either bipolar disorder or psychotic depression. All patients must have a history of psychosis as we are interested in insight in psychosis. All subjects must be cooperative, capable of lying still in a scanner for one hour and capable of performing the experimental tasks.

Exclusion criteria

Patients may not use classical antipscychotic medication as it has been shown that this type of medication can influence the activation in the frontal cortices. Furthermore, patients may use a maximum of three Lorazepam equivalents, since they must be alert enough to perform the experimental tasks. Patients must be stable on their current medication and may not have had a change in medication in the week before scanning. In addition, patients may not have the diagnosis schizoaffective disorder as this diagnosis has been controversial, difficult to diagnose and patients who have had this diagnosis are often diagnosed with schizophrenia later in life. All subjects may not have a 'relevant' neurological disorder affecting the Central Nervous System for which they are treated nor may the psychiatric diagnosis have a somatic origin.

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:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-06-2009
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	12-01-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-06-2012
Application type:	Amendment
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	NL25295.042.08