# Brain Interaction of Cognition and Emotion in Patients with Schizophrenia: experiments in search of a common brain mechanism using functional magnetic resonance imaging (fMRI)

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To investigate whether patients with schizophrenia show reliable and consistent brain activations as measured with fMRI to two different stimulation paradigms and wether they differ in terms of the patterns or the intensity of activation as compared...

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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-OMON30747

**Source**
ToetsingOnline

**Brief title**
BICEPS

### Condition

- Schizophrenia and other psychotic disorders

**Synonym**
psychosis, Schizophrenia

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** cognition, emotion, fMRI, schizophrenia

## Outcome measures

### Primary outcome

Group differences in pattern or intensity of activation between the group of

patients and healthy controls as measured by fMRI. Influence of medication on

pattern or intensity of activation in the group of patients with schizophrenia

### Secondary outcome

None.

# Study description

### Background summary

Cognition and emotion are two basic functions of humans which subserve recognizing inner and outer environment as well as goal directed behaviour in order to react on certain changes of the environment. Many studies examined human behaviour and the underlying brain mechanisms focusing only on one of these functions, namely cognition or emotion. It has become clearer in the last years that both functions are closely connected. Several approaches have been used to look for the interaction of cognition and emotion, for example, the emotional Stroop task, the influence of emotional valence or arousal on memory, positive or negative feedback etc.
In patients with schizophrenia both functions can be disturbed. Core symptoms of schizophrenia are besides the well known phenomena as hallucinations, delusions and disorganisation changes in affect and mood, but also in cognitive processes, for example working memory, attention, detection of perceptual differences, or detection of emotions.
So, it seems to be important to examine the interaction between the two functions in patients with schizophrenia focusing on the underlying brain process using fMRI.

In fMRI studies it has been shown that there are many parameters which may influence the results, for example the scanner itself, parameters of the scanning sequences used, statistical methods or baseline conditions. Furthermore the actual state of patients as well as medication may have an influence on fMRI results. The here presented study therefore addresses not only the disease process itself but also the effect of specific medication on the fMRI results by restricting the population of patients with schizophrenia to three groups, that is, medication free, use op haloperidol or clozapine.

**Study objective**

To investigate whether patients with schizophrenia show reliable and consistent brain activations as measured with fMRI to two different stimulation paradigms and wether they differ in terms of the patterns or the intensity of activation as compared to healthy controls.
a. Are there differences in activation of the prefrontal lobe, parietal lobe and limbic regions between patients with schizophrenia and healthy controls during a working memory paradigm comprising identiy of faces with emotional faces.
b. Are there differences in activation of medial prefrontal regions, limbic regions, the basal ganglia and the nucleus accumbens between patients with schizophrenia and healthy controls during a time estimation task with faces (positive or negative emotional expression) as feedback.

**Study design**

The paradigm comprises two neuropsychological tasks:
1. The first task comprises a working memory paradigm designed as an event-related Sternberg-Paradigm. Each trial comprises the short presentation of 2 or 3 faces (sample) followed by a delay of 6 seconds. Thereafter another face will appear for 2 seconds (target). Subjects have to decide whether the target face has been displayed in the sample or not. Faces will vary in identity or in emotional expression, so the study has a 2 (identity vs. emotion) x 2 (load) factorial design.
2. The second task comprises a time estimation task. Subjects are requested to look at a blank screen. Starting from the appearance of an exclamation mark on the screen subjects are asked to press a button when - following their subjective estimation - one second has passed. They will receive feedback using positive or negative emotional faces which signal the correctness of their response. Using a "self-learning" algorithm time spans, which will be assigned as correct or incorrect, are dependent of the performance of subjects. As better a subject performs the task the narrower the time spans will get, and the worse a subject performs the wider the time spans will get. This strategy is chosen in order to guarantee the same amount of positive and negative feedback signals.

### Intervention

None.

### Study burden and risks

The experiment will be performed in one session lasting about 1.5 hours. Patients and healthy controls will undergo an fMRI measurement. There will be no specific risk due to the measurement if the standard safety instructions for fMRI measurement are followed. The measurement is non-invasive and there is no exposure to X-ray or radioactivity. Patients and healthy controls are forced to lie into the tube of the scanner. Some of them may perceive this position as uncomfortable. Further causes the fMRI measurements are noisy, and this may cause in some subjects to experience a short lasting headache. Therefore subjects will wear ear plug during the measurement, a standard safety procedure during clinical MRI measurement. There are no other specific risks.

## 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

All patients (treated with clozapine or haloperidol or untreated) with a diagnosis of *first episode psychosis*, suggestive for the diagnosis schizophrenia are eligible to participate in the study. Age between 18 and 40 years

### Exclusion criteria

Any neurological, cardiovascular, and respiratory diseases; claustrophobia, pregnancy; other relevant psychiatric disorders; MRI contraindications. Subjects will also be excluded when they cannot understand the Dutch language sufficiently to understand the purposes and implications of the experiment.

## Study design

### Design

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| 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

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 22-03-2007 |
| Enrollment: | 75 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 20-03-2007 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

# 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 | NL14619.078.06 |