## Metacognitive skill training for schizophrenic patients

Submission date	Recruitment status	Prospectively registered		
22/12/2006	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
26/01/2007	Completed	[X] Results		
<b>Last Edited</b> 07/01/2019	Condition category  Mental and Behavioural Disorders	Individual participant data		

#### Plain English summary of protocol

Not provided at time of registration

## Contact information

#### Type(s)

Scientific

#### Contact name

Dr Steffen Moritz

#### Contact details

University Medical Center Hamburg-Eppendorf Martinistrasse 52 Hamburg Germany 20246

## Additional identifiers

#### Protocol serial number

DFG MO 969/6-1 & R03418/1-1

## Study information

#### Scientific Title

Metacognitive skill training for schizophrenic patients

#### Study objectives

1. Primary objective: assessment of schizophrenic positive symptoms before and after intervention (hypothesis: accelerated symptom decline under experimental intervention)

2. Secondary objective: assessment of metacognitive deficits assumed to underlie delusion formation in schizophrenia before and after intervention (hypothesis: accelerated amelioration of metacognitive deficits under experimental intervention)

Please note that as of 01/11/2012, the target number of participants was updated from 300 to 150, due to an error in the original application

## Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Local ethics committee in Hamburg, 13th November 2006 (ref: 2612).

#### Study design

Interventional randomised controlled observer-blinded parallel-group multicentre study.

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Schizophrenia

#### **Interventions**

Experimental intervention:

MetaCognitive skill Training (MCT) focusing on delusion-relevant metacognitive biases in schizophrenia.

#### Control intervention:

Cognitive remediation (computer-supported cognitive training program [COGPACK]).

Duration of intervention per patient: four weeks; sessions are scheduled twice weekly.

#### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome(s)

Current primary outcome measure as of 01/11/2012:

A delusion score derived from the Positive and Negative Syndrome Scale (PANSS): sum score of items p1 (delusions), p5 (grandiosity) and p6 (suspiciousness)

Previous primary outcome measures until 01/11/2012:

- 1. Decline on PANSS positive subscale from T1 (baseline) to T2 (four weeks/assessment immediately after the end of intervention)
- 2. Conventional algorithm (i.e., sum of PANSS positive items one to seven)

#### Key secondary outcome(s))

- 1. Improvement of dysfunctional metacognitive biases (i.e., self-serving bias, jumping to conclusions bias, incorrigibility, over-confidence in errors, enhanced need for closure)
- 2. Subsequent to intervention represents secondary outcome parameter (i.e., difference T1-T2)

Secondary analyses will include follow-up.

#### Completion date

31/12/2009

## **Eligibility**

#### Key inclusion criteria

- 1. Patients diagnosed with schizophrenia spectrum disorder
- 2. Current or prior delusional symptoms
- 3. Informed consent
- 4. Clinical stability

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### Key exclusion criteria

- 1. Age beyond 65
- 2. Severe brain damage
- 3. Intelligence Quotient (IQ) less than 70
- 4. More than or equal to five for ratings on hostility and non-cooperativeness and more than or equal to six on suspiciousness according to Positive And Negative Symptoms Scale (PANSS) interview
- 5. Incapacity to give informed consent

#### Date of first enrolment

01/12/2006

#### Date of final enrolment

31/12/2009

## Locations

#### Countries of recruitment

Germany

# Study participating centre University Medical Center Hamburg-Eppendorf Hamburg Germany 20246

## Sponsor information

#### Organisation

German Research Foundation (DFG)/Federal Ministry of Education and Research (BMBF) (Germany)

#### **ROR**

https://ror.org/018mejw64

## Funder(s)

## Funder type

Government

#### Funder Name

Deutsche Forschungsgemeinschaft

#### Alternative Name(s)

German Research Association, German Research Foundation, Deutsche Forschungsgemeinschaft (DFG), DFG

## **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

National government

#### Location

Germany

#### **Funder Name**

Bundesministerium für Bildung und Forschung

#### Alternative Name(s)

Federal Ministry of Education and Research, BMBF

## **Funding Body Type**

Government organisation

## Funding Body Subtype

National government

#### Location

Germany

## **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2014		Yes	No
Results article	results	01/06/2018		Yes	No