ISRCTN95205723 https://doi.org/10.1186/ISRCTN95205723

# 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 |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 07/01/2019 | Mental and Behavioural Disorders | |

**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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet

## 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 measure
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)

### Secondary outcome measures
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.

### Overall study start date
01/12/2006

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
150

### 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)

### Sponsor details
Kennedyallee 40
Bonn
Germany
53175

### Sponsor type
Government

### ROR
https://ror.org/018mejw64

## Funder(s)

### Funder type

Government

**Funder Name**
Deutsche Forschungsgemeinschaft

**Alternative Name(s)**
German Research Association, German Research Foundation, 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

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

## 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 |