

Metacognitive skill training for schizophrenic patients

Submission date 22/12/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 26/01/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 07/01/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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/018meiw64>

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