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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

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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).

Primary study design
Interventional

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

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 Research, Technology and Space, Bundesministerium für Bildung und Forschung, 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