

Cognitive behavioural treatment for persistent positive symptoms in psychotic disorders

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
04/12/2006	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
26/01/2007	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
01/11/2022	Mental and Behavioural Disorders	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Tuebingen
Germany
72076

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

-

Acronym

POSITIVE

Study objectives

Cognitive Behavioural Treatment (CBT) is more efficacious in reducing positive symptoms than Supportive Therapy (ST).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Medical Faculty, University of Tuebingen; date of approval: 27 October 2006

Study design

Randomised, single blind, parallel group, prospective, controlled study comparing a specific treatment with an unspecific, placebo-attention control group

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Psychotic disorders (schizophrenia, schizopreniform, schizoaffective and delusional disorders)

Interventions

Cognitive Behavioural Treatment versus Supportive Therapy

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Primary endpoint for efficacy: PANSS positive syndrome (sum of items P1-P7), assessed post treatment (T9).

Key secondary outcome(s)

Key secondary endpoints:

1. Additional symptom ratings (e.g. PSYRATS)
2. Social functioning
3. Illness related events
4. Quality of life
5. Questionnaires about self schemata and interpersonal schemata
6. Direct and indirect costs

Assessment of safety:

1. Death
2. Suicidal behaviour
3. Severe depressive symptom exacerbation

Completion date

31/12/2008

Eligibility

Key inclusion criteria

1. Schizophrenia, schizophreniform, schizoaffective, delusional disorders (according to Diagnostic and Statistical Manual of Mental Disorders - fourth edition [DSM-IV])
2. Score of four or more on the Positive and Negative Syndrome Scale (PANSS)-items delusions or hallucinations
3. Presence of these symptoms for at least three months

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Total final enrolment

233

Key exclusion criteria

1. Substance abuse or substance dependence as primary clinical problem
2. Organic brain disease

Date of first enrolment

01/01/2007

Date of final enrolment

31/12/2008

Locations

Countries of recruitment

Germany

Study participating centre

Osianderstr. 24

Tuebingen

Germany

72076

Sponsor information

Organisation

University Hospital Tuebingen (Germany)

ROR

<https://ror.org/00pjgxh97>

Funder(s)

Funder type

Research organisation

Funder Name

German Ministry of Education and Research (Bundesministerium für Bildung und Forschung, BMBF; 01GV0618)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	secondary analysis	10/02/2020	12/02/2020	Yes	No
<u>Results article</u>	secondary analysis	23/11/2020	25/11/2020	Yes	No