

Cognitive behavioural treatment for persistent positive symptoms in psychotic disorders

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

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, schizophreniform, 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?
Results article	secondary analysis	10/02/2020	12/02/2020	Yes	No
Results article	secondary analysis	23/11/2020	25/11/2020	Yes	No