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Cognitive behavioural treatment for persistent positive symptoms in psychotic disorders

Submission date	Recruitment status	[ ] Prospectively registered
04/12/2006	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
01/11/2022	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 Commitee 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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/01/2007

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
260

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)

Sponsor details
Geissweg 3
Tuebingen
Germany
72076

Sponsor type
University/education

Website
http://www.medizin.uni-tuebingen.de

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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