ISRCTN29242879 https://doi.org/10.1186/ISRCTN29242879

# Cognitive behavioural treatment for persistent positive symptoms in psychotic disorders

| Submission date | Recruitment status |
|---|---|
| 04/12/2006 | No longer recruiting |
| **Registration date** | **Overall study status** |
| 26/01/2007 | Completed |
| **Last Edited** | **Condition category** |
| 01/11/2022 | Mental and Behavioural Disorders |

✓ Retrospectively registered
? Protocol not yet added
? SAP not yet added
✓ Results added
? Raw data not yet added
✓ Study completed

**Plain English Summary**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
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**Contact details**
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Tuebingen
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72076

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Protocol/serial number**
N/A

## Study information

**Scientific Title**

-

## Acronym
POSITIVE

## Study hypothesis
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

## Condition
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

### Overall study end date
31/12/2008

## Eligibility

### Participant 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

### Participant exclusion criteria
1. Substance abuse or substance dependence as primary clinical problem
2. Organic brain disease

### Recruitment start date
01/01/2007

**Recruitment end date**
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 |