

Cognitive behavioural treatment of negative symptoms in patients with schizophrenic disorders

Submission date 16/09/2005	Recruitment status No longer recruiting	☒ Prospectively registered
Registration date 21/11/2005	Overall study status Completed	☐ Protocol
Last Edited 06/09/2011	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☒ Results
		☐ 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

KL1179/3-1

Study information

Scientific Title

Acronym

TONES

Study objectives

Cognitive Behavioural Treatment (CBT) is more efficacious in reducing negative symptoms (PANSS modified negative symptom factor) in schizophrenic disorders than Cognitive Remediation (CR)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Schizophrenia

Interventions

Cognitive Behavioural Treatment versus Cognitive Remediation

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

PANSS Modified Negative Factor (N1, N2, N3, N4, N6, G7, G16)

Key secondary outcome(s)

1. Illness related events
2. Scale for the Assessment of Negative Symptoms (SANS)
3. Calgary Depression Scale for Schizophrenia (CDSS)
4. Clinical Global Impression (CGI)
5. Lancashire Quality of Life Profile (LQLP)
6. Social Status
7. Medication Compliance
8. Symptom Checklist 90 Revised (SCL-90-R)
9. Frontal Eye Fields (FEF)
10. Frankfurt Self-concept Scale (FSKN)
11. Neuropsychological assessment

Completion date

31/12/2007

Eligibility

Key inclusion criteria

1. Schizophrenia (Diagnostic and Statistical Manual of Mental Disorders - fourth edition [DSM-IV] 295.1, 295.2, 295.3, 295.4, 295.6, 295.9)
2. PANSS Modified Negative Syndrome Score ≥ 10
3. Fluency of German language

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Severe positive symptoms (any item of the standard PANSS positive scale [P1, P2, P3, P4, P5, P6, P7] ≥ 6)
2. Severe depression as indicated by PANSS G6 ≥ 6
3. Extrapyrarnidal symptoms
4. Age below 18 or over 55
5. Organic disorder interfering with the central nervous system
6. Verbal IQ < 80
7. Diagnosis of substance abuse or substance dependence according to DSM-IV/Structured Clinical Interview for Depression (SCID-I) as primary clinical problem
8. Travel time to the study centre of more than 1 hour

Date of first enrolment

01/01/2006

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

Germany

Study participating centre

Department of Psychiatry and Psychotherapy
Tuebingen
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Sponsor information

Organisation

University Hospital Tuebingen (Germany)

ROR

<https://ror.org/00pjgxm97>

Funder(s)

Funder type

Research organisation

Funder Name

German Research Foundation (Deutsche Forschungsgemeinschaft) (Germany), grant KL1179/3-1

Results and Publications

Individual participant data (IPD) sharing plan

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	results	01/09/2011		Yes	No