ISRCTN25455020 https://doi.org/10.1186/ISRCTN25455020

Cognitive behavioural treatment of negative symptoms in patients with schizophrenic disorders

Submission date	Recruitment status	[X] Prospectively registered
16/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/11/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/09/2011	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Stefan Klingberg

Contact details
Department of Psychiatry and Psychotherapy
Osianderstr. 24
Tuebingen
Germany
D-72076
stefan.klingberg@med.uni-tuebingen.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Schizophrenia

Interventions
Cognitive Behavioural Treatment versus Cognitive Remediation

Intervention Type
Other

Phase
Not Specified

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

Secondary outcome measures
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

Overall study start date
01/01/2006

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

Age group
Adult

Sex
Both

Target number of participants
198

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. Extrapyramidal 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
Germany
D-72076

Sponsor information

Organisation
University Hospital Tuebingen (Germany)

Sponsor details
Post Box 2669
Tuebingen
Germany
D-72016

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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