Study Of Cognitive ReAlignment Therapy in Early Schizophrenia

Submission date	Recruitment status	Prospectively registered
23/10/2000	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
23/10/2000	Completed	[X] Results
Last Edited	Condition category	Individual participant data
23/09/2009	Mental and Behavioural Disorders	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof SW Lewis

Contact details

School of Psychiatry and Behavioural Science University of Manchester Withington Hospital West Didsbury Manchester United Kingdom M20 8LR

Additional identifiers

Protocol serial number G9519373

Study information

Scientific Title

Acronym

SOCRATES

Study objectives

To evaluate the effectiveness of cognitive behaviour therapy in parallel with drug treatments as usual in early acute schizophrenia. The hypothesis is that CBT is an acceptable adjunct to drug treatment which will accelerate resolution of target psychotic symptoms and reduce relapse.

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

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Neurosciences, psychiatry

Interventions

Cognitive behaviour therapy/drug treatments

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

- 1. Change on core symptom scores on hallucination and delusion rating scales
- 2. Change in total symptoms scores on PANSS
- 3. Time to criterion of 50% recovery operationally defined -
- 4. Number of days in hospital before 1st discharge and during follow-up
- 5. Time to relapse
- 6. Follow-up symptom and outcome scores at 3.9 and 18 months

Key secondary outcome(s))

Not provided at time of registration

Completion date

31/03/2000

Eligibility

Key inclusion criteria

Consecutive sample of in- or day-patients admitted with 1st and 2nd episode schizophrenia aged 18-65. Further inclusion criteria:

- 1. Able to give informed consent
- 2. Meet Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSMIV) diagnostic criteria for schizophrenia, schizophreniform or schizoaffective disorder with at least a 1 month history of positive symptoms
- 3. No significant history of organic brain disease or substance misuses for major aetiological factor for psychosis
- 4. Positive and negative syndrome scale (PANSS) for schizophrenia score of at least 4 on item hallucinatory behaviour and/or item delusions
- 5. Score of less than 5 on PANSS item conceptual disorganisation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/04/1996

Date of final enrolment

31/03/2000

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

School of Psychiatry and Behavioural Science

Manchester United Kingdom M20 8LR

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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	01/09/2002		Yes	No