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Study Of Cognitive ReAlignment Therapy in Early Schizophrenia

Submission date	Recruitment status
23/10/2000	No longer recruiting
Registration date	**Overall study status**
23/10/2000	Completed
Last Edited	**Condition category**
23/09/2009	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Neurosciences, psychiatry

Interventions
Cognitive behaviour therapy/drug treatments

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/1996

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Not Specified

Target number of participants
236

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
England

United Kingdom

Study participating centre
School of Psychiatry and Behavioural Science
Manchester
United Kingdom
M20 8LR

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.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

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	01/09/2002		Yes	No