

# Study Of Cognitive ReAlignment Therapy in Early Schizophrenia

<b>Submission date</b> 23/10/2000	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/10/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 23/09/2009	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

**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, Medical Research Committee and Advisory 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				

[Results article](#)

01/09/2002

Yes

No