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The effectiveness of cognitive remediation therapy (CRT) for patients with schizophrenia

Submission date	Recruitment status	[ ] Prospectively registered
23/01/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/01/2010	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RDC01881

Study information

Scientific Title

Study objectives
Patients with schizophrenia are not only concerned about the positive symptoms of the disorder but are also distressed by the cognitive deficits associated with the disorder. Attention, concentration and memory are also associated with poor outcome with those patients with the severest deficits being in need of high levels of service support. The therapy under investigation in this trial was designed to have a direct effect on cognition which will then impact on daily functioning and perceived quality of life. The project is a randomised controlled trial of this innovative treatment, cognitive remediation therapy (CRT). Previous studies have shown that CRT has significant effects on cognitive functioning in patients with severe cognitive difficulties and that when this improvement reaches a generalised threshold there are effects on social functioning. The purpose of this trial is to widen its application to those whose cognitive performance is not so poor, to test predictive factors for outcome and assess the effects of therapy on a specific skill, shopping. In addition, the trial contains a health economic aspect which will allow cost-effectiveness to be assessed. The results will provide further detail on the effects and applicability of this treatment to the wider population of people with schizophrenia and will aid its further implementation into the NHS.

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
Mental and behavioural disorders: Schizophrenia and other psychoses

Interventions

1. Cognitive remediation therapy
2. Standard care

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
All have been chosen for their good reliability and validity and use in this population of patients.
i. Cognitive outcomes - the results of neuropsychological tests (see plan of investigation for details)
ii. Social Behaviour - DEX independent questionnaire, Social Behaviour Schedule and Test of Grocery Skills
iii. Symptom outcome - PANNS
iv. Quality of Life - MANSA
v. Self esteem - Rosenberg self esteem schedule
vi. Service contact - Client Service Receipt Inventory
Process measures - These forms allow ratings of the level of performance achieved in each session, with reference to the individual tasks carried out in the session as well as at the end of each module. They have established inter-rater reliability as well as face validity.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2000

Completion date
01/11/2003

Eligibility

Key inclusion criteria
1. In contact with local psychiatric services for at least two years
2. Diagnosis of schizophrenia based on The Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSMIV)
3. Evidence of some cognitive difficulties (rated as poor on either memory or cognitive flexibility)
4. Evidence of social functioning problems (scored on at least one problem on Social Behaviour Scale)

Participant type(s)
Patient

Age group
Not Specified

Sex

Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/11/2000

Date of final enrolment
01/11/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Psychiatry
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
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Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive London (UK)

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	01/05/2007		Yes	No