

Cognitive remediation for young people with schizophrenia

Submission date

20/03/2006

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

05/05/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

07/12/2010

Condition category

Mental and Behavioural Disorders

☐ 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

SCYP 97/06

Study information

Scientific Title

Study objectives

Cognitive remediation will improve cognition relative to treatment as usual

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the South London and Maudsley Ethics Committee as an amendment to a previous application, reference number: 008/99 and the North East London Ethics Committee Oct 02, reference number: P/02/192

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 remediation therapy versus usual care

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Cognitive flexibility (number of categories achieved on the Wisconsin Card Sort Test [WCST] Heaton et al.)

2. Memory (raw score from Digit Span: Wechsler Adult Intelligence Scale-III [WAIS-III] Wechsler, 1981)
3. Planning (modified six elements)

Secondary outcome measures

1. Social Behaviour Schedule ([SBS] Wykes and Sturt, 1986) for social functioning
2. Brief Psychiatric Rating Scale (for symptoms) using Lukoff et al. version and Shaffer Factor Scores
3. Quality of Life Scale (for social inclusion)
4. Rosenberg Self Esteem Scale (Rosenberg, 1965)

Overall study start date

30/09/1998

Completion date

30/09/2004

Eligibility

Key inclusion criteria

1. A diagnosis of schizophrenia according to the Diagnostic and Statistical Manual, 4th (DSM IV); had a first episode while still a teenager and their duration of illness was 3 years or less
2. Cognitive difficulties in cognitive flexibility (below the 16th centile on the Wisconsin Card Sort Test) and/or memory (poor performance on the Rivermead Behavioural Memory Test)
3. Difficulties in social functioning (at least one problem on the Social Behaviour Scale)
4. Stable medication, in terms of type and dose, for at least one month prior to inclusion

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

40

Key exclusion criteria

1. Evidence of organic brain disorder (e.g. epilepsy)
2. A diagnosis of current substance abuse as defined by the DSM IV
3. A plan to change medication during the trial

Date of first enrolment

30/09/1998

Date of final enrolment

30/09/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department of Psychology

London

United Kingdom

SE5 8AF

Sponsor information

Organisation

King's College London (UK)

Sponsor details

De Crespigny Park

London

England

United Kingdom

SE5 8AF

Sponsor type

University/education

Website

<http://www.iop.kcl.ac.uk>

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

Charity

Funder Name

Mental Health Foundation SCYP 97/06, research support account PAH9009

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 | 01/08/2007 | | Yes | No |