

Neural correlates of response to COGnitive behaviour therapy in SCHIZophrenia: a functional magnetic resonance imaging investigation

Submission date 22/07/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/07/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/11/2012	Condition category 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

Dr Veena Kumari

Contact details

King's College London
Institute of Psychiatry
PO78, Psychology
De Crespigny Park
Denmark Hill
London
United Kingdom
SE5 8AF
+44 (0)20 7848 0233
v.kumari@iop.kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

067427

Study information

Scientific Title

Acronym

COGSCHIZ

Study objectives

1. Does successful treatment of symptoms of schizophrenia produce measurable changes at the brain level?
2. Are there brain predictors of the clinical response to cognitive behaviour therapy in schizophrenia?

Please note that as of 19/01/2007 the anticipated end date of this trial has now been shortened to 30/03/2007. The initial anticipated end date of your trial was 30/06/2007.

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)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Schizophrenia

Interventions

Functional Magnetic Resonance Imaging (MRI) will be applied to investigate brain functions of 60 patients with schizophrenia, 30 of whom will undergo cognitive behaviour therapy. All patients will be scanned twice, 8 to 9 months apart, during a series of tasks known or likely to be sensitive to symptoms of schizophrenia.

Control data will also be obtained from 20 patients with schizophrenia who have shown a good response to their antipsychotic medication and 20 healthy subjects.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Blood-oxygenation-level-dependent response in cortical and sub-cortical regions
2. Symptom scores

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/11/2002

Completion date

30/03/2007

Eligibility**Key inclusion criteria**

Patients with a diagnosis of schizophrenia:

1. Who have shown partial or complete resistance to typical or atypical drug therapy
2. Are right handed
3. Have no history of neurological conditions or head injury
4. Can tolerate scanning
5. Can provide written consent

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

100

Key exclusion criteria

Evidence of primary drug or alcohol abuse or consumption of alcohol or street drugs within 24 hours of scheduled testing.

Date of first enrolment

01/11/2002

Date of final enrolment

30/03/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

King's College London

London

United Kingdom

SE5 8AF

Sponsor information

Organisation

King's College London (UK)

Sponsor details

c/o Dr Gill Dale

Research and Development Office P005

Institute of Psychiatry

De Crespigny Park

London

England

United Kingdom

SE5 8AF

+44 (0)20 7848 0675

g.dale@iop.kcl.ac.uk

Sponsor type

University/education

Website

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

ROR

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

Funder(s)

Funder type

Charity

Funder Name

The Wellcome Trust (UK) (grant ref: 067427)

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	01/08/2011		Yes	No