Promoting personal recovery from psychosis: A randomised controlled trial in first episode 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 28/01/2010	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers RGC00447

Study information

Scientific Title

Study objectives

The objective of the study is to evaluate whether a form of cognitive therapy (recovery intervention) is an effective intervention to promote personal adjustment to psychosis and reduce depression, trauma and other characteristic negative consequences of psychosis.

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 and other psychoses

Interventions

The intervention group will receive cognitive therapy over a 6 month period
The control group will receive treatment as usual

Intervention Type Other

Phase Not Applicable

Primary outcome measure

- 1. Post-psychotic depression, suicidal ideation (Calgary scale)
- 2. Symptoms of Post Traumatic Stress Disorder (Impact of Events scale)
- 3. Adaptation to psychosis
- 4. Particularly perceived control over psychosis

Secondary outcome measures

Not provided at time of registration

Overall study start date 01/05/2001

Completion date

01/05/2003

Eligibility

Key inclusion criteria

Patients conforming to International Statistical Classification of Diseases and Related Health Problems, Tenth revision (ICD-10) schizophrenia or related disorder

Participant type(s) Patient

Age group Adult

Sex Both

Target number of participants 66 (added 28/01/10; see publication)

Key exclusion criteria Does not match inclusion criteria

Date of first enrolment 01/05/2001

Date of final enrolment 01/05/2003

Locations

Countries of recruitment England

United Kingdom

Study participating centre North Birmingham Mental Health NHS Trust Birmingham United Kingdom B6 5UG

Sponsor information

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

Sponsor details The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

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

Funder(s)

Funder type Government

Funder Name NHS Executive West Midlands (UK)

Results and Publications

Publication and dissemination plan Not provided at time of registration

Intention to publish date

IPD sharing plan summary Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	01/06/2009		Yes	No