

A random controlled trial to compare the efficacy of a brief psycho-educational programme with standard care plus bibliotherapy for individuals with Bipolar Disorder at high risk for relapse.

Submission date 30/09/2005	Recruitment status Stopped	☐ Prospectively registered
		☐ Protocol
Registration date 30/09/2005	Overall study status Stopped	☐ Statistical analysis plan
		☐ Results
Last Edited 31/03/2011	Condition category Mental and Behavioural Disorders	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Mariajose Gutierrez

Contact details
Co-ordinated Psychological Treatments Service (CPTS)
The Ladywell Unit
University Hospital Lewisham
Lewisham High street
London
United Kingdom
SE13 6LH
+44
mjgros@yahoo.co.uk

Additional identifiers

Protocol serial number
N0534139816

Study information

Scientific Title

Study objectives

To determine if a psycho-educational intervention is associated with significant clinical improvements

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Mental and Behavioural Disorders: Bipolar disorders

Interventions

Brief psycho-educational programme vs standard care plus biblio-therapy

Added 21 July 2008: trial discontinued in 2005

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Time to first relapse as assessed by independent blind reviewer.

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/10/2007

Eligibility

Key inclusion criteria

Subjects with bipolar disorder in contact with 3CMHT in Lewisham catchment area, inpatient units at Ladywell or by direct recruitment by GPs.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. Subjects with co-morbid schizophrenia, schizo-affective disorder and psychosis
2. Subjects with severe borderline or antisocial personality disorder
3. Subjects with primary substance abuse disorder
4. Subjects suffering from an organic brain syndrome
5. Participants who currently meet DSM-IV criteria for mania, hypomania or mixed state (plus B-R > 15, &/or HRSD > 17). These patients could be admitted to the study in a later stage once they are euthymic, or mildly depressed or hypomaniac.
6. Subjects unable to read or write English
7. Subjects unable to give informed consent

Date of first enrolment

01/02/2004

Date of final enrolment

31/10/2007

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Co-ordinated Psychological Treatments Service (CPTS)

London

United Kingdom

SE13 6LH

Sponsor information

Organisation

Department of Health

Funder(s)**Funder type**

Government

Funder Name

Lambeth, Southwark and Lewisham Primary Care Trusts (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration