ISRCTN45002938 https://doi.org/10.1186/ISRCTN45002938

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

**Submission date**
30/09/2005

**Registration date**
30/09/2005

**Last Edited**
31/03/2011

**Recruitment status**
Stopped

**Overall study status**
Stopped

**Condition category**
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

**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**
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

**Study design**
Randomised controlled trial

**Primary study design**
Interventional

**Secondary study design**
Randomised controlled trial

**Study setting(s)**
Not specified

**Study type(s)**
Not Specified

**Participant information sheet**

**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 measure
Time to first relapse as assessed by independent blind reviewer.

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/02/2004

### 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

### Age group
Not Specified

### Sex
Not Specified

### Target number of participants
60

### 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**
England

United Kingdom

**Study participating centre**
**Co-ordinated Psychological Treatments Service (CPTS)**
London
United Kingdom
SE13 6LH

# Sponsor information

**Organisation**
Department of Health

**Sponsor details**
Richmond House
79 Whitehall
London
United Kingdom
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**Sponsor type**
Government

**Website**
http://www.dh.gov.uk/Home/fs/en

# Funder(s)

**Funder type**
Government

**Funder Name**
Lambeth, Southwark and Lewisham Primary Care Trusts (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