

# 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.

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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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

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

## 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