

# Randomised controlled trial of efficacy of teaching patients with bipolar disorder to identify early symptoms of relapse and obtain treatment

**Submission date**

23/01/2004

**Recruitment status**

No longer recruiting

**Registration date**

23/01/2004

**Overall study status**

Completed

**Last Edited**

01/06/2009

**Condition category**

Mental and Behavioural Disorders

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

**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

N/A

## Study information

### Scientific Title

### Study objectives

To determine the efficacy of teaching patients with bipolar disorder (manic-depressive psychosis) to identify early symptoms of relapse and seek prompt treatment from health services.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

The study was approved by a medical ethics committee in each NHS trust. Each patient gave written informed consent to the trial.

### 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

7 - 12 intervention treatment sessions from a research psychologist plus routine care versus routine care only.

### Intervention Type

Other

### Phase

Not Specified

### Primary outcome measure

1. Time to first manic or depressive relapse
2. Number of manic or depressive relapses
3. Social functioning examined by standardised interviews every six months for 18 months

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/03/1994

**Completion date**

01/04/1997

## Eligibility

**Key inclusion criteria**

1. A lifetime diagnosis of bipolar disorder elicited by a trained research assistant using a standardised psychiatric interview
2. Two or more relapses
3. One in the previous 12 months
4. Aged 18 to 75 years

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

69

**Key exclusion criteria**

1. An inability to read or write in English
2. Drug or alcohol misuse or dependence as a primary problem
3. An organic cerebral cause for bipolar disorder, e.g., multiple sclerosis or stroke

**Date of first enrolment**

01/03/1994

**Date of final enrolment**

01/04/1997

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Department of Community Psychiatry**

Manchester

United Kingdom

M20 8LR

## **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 North West (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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	16/01/1999		Yes	No