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

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
23/01/2004		☐ Protocol		
Registration date 23/01/2004	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 01/06/2009	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

#### Contact name

Dr Richard Morriss

#### Contact details

Department of Community Psychiatry University of Manchester Withington Hospital Manchester United Kingdom M20 8LR

#### Additional identifiers

**Protocol serial number** 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

#### Study type(s)

Treatment

#### 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(s)

- 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

#### Key secondary outcome(s))

Not provided at time of registration

#### 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** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

Αll

#### 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

**United Kingdom** 

England

# 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)

# Funder(s)

#### Funder type

Government

#### Funder Name

NHS Executive North West (UK)

### **Results and Publications**

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?
Results article	results	16/01/1999		Yes	No