

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	☐ Prospectively registered
Registration date 23/01/2004	Overall study status Completed	☐ Protocol
Last Edited 01/06/2009	Condition category Mental and Behavioural Disorders	☐ 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

Dr Richard Morriss

Contact details

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

Additional identifiers

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.

Primary study design

Interventional

Study design

Randomised controlled trial

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

All

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

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