

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?
Results article	results	16/01/1999		Yes	No