

A randomised controlled trial of group psychoeducation with bipolar affective disorder patients.

Submission date 30/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 30/09/2005	Overall study status Completed	☐ Protocol
Last Edited 08/04/2014	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ 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

Protocol serial number

N0573157682

Study information

Scientific Title

Study objectives

Does group psychoeducation reduce time to manic relapse, number of manic relapses, and improve social functioning in patients with bipolar affective disorder?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Mental and Behavioural Disorders: Bipolar disorders

Interventions

Randomised controlled trial, research with outpatients

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Time to manic relapse and number of manic relapses in each 6 month period. Relapse will be defined as SCID criteria for hypomania or mania. Raters (who will be blind to the randomisation) will keep in close contact with patients, keyworkers and RMOs to ensure that relapses are spotted.
2. Social functioning determined by standardised ratings at 0, 6, 12, and 18 months after randomisation.
3. MADRS and Young scores will be determined at 0, 6, 12 and 18 months after randomisation.

Key secondary outcome(s)

In order to provide clarification of how patients have progressed throughout the course of the study patients in both conditions will be keeping a mood diary on a daily basis. The mood diary lists a variety of symptoms associated with bipolar disorder. Each day patients will rate the severity of each of the symptoms on a 4 point scale (0=none, 4=severe).

Completion date

30/11/2005

Eligibility

Key inclusion criteria

70 bipolar patients from Newcastle and North Tyneside.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. Patient with learning disability, axis 1 co-morbidity, alcohol or drug dependency
2. Serious suicidal intent
3. Personality disorder
4. Organic brain disorder
5. Patients undergoing any concurrent psychological therapy
6. Bipolar disorder with a seasonal pattern

Date of first enrolment

01/12/2003

Date of final enrolment

30/11/2005

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Academic Psychiatry

Newcastle upon Tyne

United Kingdom

NE1 4LP

Sponsor information**Organisation**

Department of Health

Funder(s)

Funder type

Government

Funder Name

Newcastle, North Tyneside and Northumberland Mental Health NHS Trust (UK), NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration