ISRCTN82941238 https://doi.org/10.1186/ISRCTN82941238

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof AH Young

Contact details
Academic Psychiatry
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
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.

Secondary outcome measures
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).

Overall study start date
01/12/2003

Completion date
30/11/2005

Eligibility

Key inclusion criteria
70 bipolar patients from Newcastle and North Tyneside.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
70

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
England

United Kingdom

Study participating centre
Academic Psychiatry
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Department of Health

Sponsor details
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.dh.gov.uk/Home/fs/en

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

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