

MRC Multicentre randomised controlled trial of cognitive behaviour therapy in bipolar affective disorder

Submission date 23/10/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/10/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/12/2017	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Ms Michaela Rodger

Contact details

Study Co-ordinator Academic Centre
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
United Kingdom
G12 OXH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G9721149

Study information

Scientific Title

MRC Multicentre randomised controlled trial of cognitive behaviour therapy in bipolar affective disorder

Study objectives

To show:

1. That Cognitive Behaviour Therapy (CBT) added to usual treatment is more efficacious than usual treatment alone in reducing relapse rates and symptom levels and improving quality of life and functioning
2. That the additional costs of CBT will be offset by reductions in direct health care costs, direct non-treatment costs and indirect costs, when compared with usual treatment alone

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

Bipolar affective disorder

Interventions

1. One group receiving cognitive behaviour therapy as well as treatment as usual
2. One group receiving only treatment as usual

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Recurrence of an episode of illness of sufficient severity to reach the Diagnostic and Statistical Manual of mental disorders fourth edition (DSM-IV) criteria for major depressive episode, manic episode or mixed episode, based on the Structured Clinical Interview (SCID) instrument
2. A longitudinal severity rating of overall symptom levels for each week since last interview (two months) based on the Longitudinal Interval Follow-up Evaluation (LIFE-II)
3. Total costs - data on all services received will be obtained using the Client/Service Receipt Inventory (CSRI; Beecham and Knapp 1992) to cover first the year prior to study entry and then every six months until the end of the follow-up period

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/07/1999

Completion date

30/04/2003

Eligibility**Key inclusion criteria**

1. Aged 18 years or more
2. Two or more episodes
3. Last episode in previous 12 months
4. Currently/last six months in contact with mental health
5. Currently asymptomatic, depression, hypomania

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

220

Key exclusion criteria

1. Cannot engage/ rapid cycling bipolar disorder (more than or equal to four episodes per year)
2. Bipolar disorder secondary to organic cause
3. Mental disorder primarily alcohol or drug related
4. Severe borderline personality disorder
5. Receiving systematic psychological treatment for bipolar disorder

- 6. Unable to read/write English
- 7. Unable to give informed consent
- 8. If the patients referred to the study knew the therapist when the therapist worked in a previous capacity, (e.g. as a community psychiatric nurse in a community mental health team looking after the patient), the patient would not be entered into the study

Date of first enrolment

01/07/1999

Date of final enrolment

30/04/2003

Locations

Countries of recruitment

United Kingdom

Study participating centre

Study Co-ordinator Academic Centre

Glasgow

United Kingdom

G12 OXH

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

20 Park Crescent

London

United Kingdom

W1B 1AL

+44 (0)20 7636 5422

clinical.trial@headoffice.mrc.ac.uk

Sponsor type

Research council

Website

<http://www.mrc.ac.uk>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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 of preliminary investigation	01/06/2003		Yes	No
Protocol article	protocol	01/06/2005		Yes	No
Results article	results	01/05/2006		Yes	No
Results article	results	01/02/2007		Yes	No