ISRCTN99884475 https://doi.org/10.1186/ISRCTN99884475

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

Submission date 23/10/2000	**Recruitment status** No longer recruiting
Registration date 23/10/2000	**Overall study status** Completed
Last Edited 05/12/2017	**Condition category** Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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