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

<b>Recruitment status</b> No longer recruiting	Prospectively registered		
	[X] Protocol		
Overall study status	Statistical analysis plan		
Completed	[X] Results		
Condition category  Mental and Rehavioural Disorders	Individual participant data		
	No longer recruiting  Overall study status  Completed		

#### 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

Protocol serial number 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

#### Study type(s)

**Not Specified** 

#### 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(s)

- 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

#### Key secondary outcome(s))

Not provided at time of registration

#### 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** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

Αll

#### 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)

## 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**

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
Results article	results	01/05/2006		Yes	No
Results article	results	01/02/2007		Yes	No
<u>Protocol article</u>	protocol	01/06/2005		Yes	No