

# Cognitive remediation therapy in bipolar disorder

<b>Submission date</b> 03/02/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 03/02/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/03/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Bipolar disorder, previously known as “manic depression”, is a serious mental illness that involves episodes of depression (extreme lows) and mania (extreme highs) or hypomania (a milder form of mania). BD can be extremely distressing for both sufferers and their loved ones, and is thought to cost the NHS around £340 million every year. The more episodes a person has the more likely they are to relapse and for quality of life to worsen, and so it is important to find new treatments that improve recovery and boost resilience to reduce further episodes. People with bipolar disorder often have difficulty with thinking skills (cognitive function) such as concentration, memory, and planning. These problems are linked with reduced response to treatment, higher relapse rates, and more difficulties in everyday life. Similar problems in people diagnosed with schizophrenia can be helped with cognitive remediation therapy (a type of therapy designed to improve cognitive function), however it is not yet known whether this would be effective in people with bipolar disorder. The aim of this investigate whether a part-computerised version of CRT, is an acceptable treatment option for people with bipolar disorder and whether it can help to improve cognitive function.

### Who can participate?

Adults with bipolar I disorder (a form of BD characterized by severe manic episodes) who are not currently experiencing manic or depressive symptoms.

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group take part in two-three weekly sessions of CRT which last for around an hour for 12 weeks, alongside their usual treatment. Participants also complete part of the therapy on a computer, so the total therapy time is around 20-40 hours over the 12 weeks. Those in the second group continue with their usual treatment only for the 12 weeks of the study. At the start of the study and then again after 12 and 24 weeks, participants complete a number of tasks involving thinking, concentration and memory to test their cognitive functioning.

### What are the possible benefits and risks of participating?

Participants may benefit from an improvement to their cognitive and everyday functioning after taking part in the study. There is a small risk that the therapy may be distressing for some

participants or that that it will not work for them. however trained therapists are available to help participants if this happens.

Where is the study run from?

1. Optima mood disorders clinic, Lambeth Hospital (UK)
2. Clinical Research Facility, King's College Hospital (UK)

When is the study starting and how long is it expected to run for?

December 2015 to December 2016

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Ms Becci Strawbridge

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## Contact information

**Type(s)**

Public

**Contact name**

Ms Becci Strawbridge

**Contact details**

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## Additional identifiers

**Protocol serial number**

19967

## Study information

**Scientific Title**

The Cognitive Remediation in Bipolar (CRiB) Study: a feasibility trial of cognitive remediation therapy in people with bipolar disorder versus treatment as usual

**Acronym**

CRiB

**Study objectives**

The aim of this study is to investigate whether cognitive remediation therapy (CRT) is an acceptable treatment and whether it is effective in improving thinking skills and everyday functioning in patients with bipolar disorder.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

London - City Road, and Hampstead, 16/10/2015, ref: 15/LO/1557

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Topic: Mental Health; Subtopic: Bipolar affective disorder; Disease: Bipolar affective disorder

**Interventions**

Participants are randomly allocated to one of two groups.

Intervention group: Intervention group: Participants receive cognitive remediation therapy (CRT) alongside their usual treatment. This involves attending approximately 2 CRT sessions per week (estimated 1 hour each) for 12 weeks, in addition to computerised exercise practice when convenient.

Control group: Participants receive their usual treatment only for 12 weeks.

All participants attend three assessment sessions, involving completion of cognitive tasks and questionnaires, at baseline, 12 and 24 weeks.

**Intervention Type**

Other

**Primary outcome(s)**

Cognitive Performance is measured at baseline, 12 and 24 weeks.

**Key secondary outcome(s)**

1. Engagement with the intervention is determined at 12 weeks
2. Level of functioning is measured at baseline 12 and 24 weeks
3. Symptom prevention is measured at baseline 12 and 24 weeks

**Completion date**

31/03/2019

# Eligibility

## Key inclusion criteria

1. Aged 18 to 65 years
2. Confirmed DSM-V diagnosis of bipolar I disorder
3. Those who have been in an euthymic state at two timepoints one week apart, defined by scores of <8 on the Hamilton Rating Scale for Depression and Young Mania Rating Scale at both timepoints

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Sex

All

## Total final enrolment

60

## Key exclusion criteria

1. Presence of a substantial neurological/neurodevelopmental disorder
2. Current diagnosis of personality disorder
3. Recent involvement with alcohol or substance abuse
4. Aged under 18 or over 65 years old
5. Severe visual or auditory problems
6. Unable to understand verbal and written instructions in English

## Date of first enrolment

10/02/2016

## Date of final enrolment

01/06/2017

# Locations

## Countries of recruitment

United Kingdom

England

**Study participating centre**  
**King's College Hospital**  
Clinical Research Facility  
Denmark Hill  
London  
United Kingdom  
SE5 9RS

**Study participating centre**  
**Lambeth Hospital**  
Optima mood disorders clinic  
Bridge House  
Landon Road  
Clapham  
London  
United Kingdom  
SW9 9NU

## **Sponsor information**

**Organisation**  
King's College London (UK)

**ROR**  
<https://ror.org/0220mzb33>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
National Institute for Health Research

**Alternative Name(s)**  
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**  
Government organisation

**Funding Body Subtype**

National government

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study is not expected to be made available due to potential issues arising regarding consent and disclosure, identification and anonymity of participants.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/03/2021	26/06/2020	Yes	No
<a href="#">Results article</a>	Exploratory study	01/07/2021	10/03/2023	Yes	No
<a href="#">Protocol article</a>	protocol	29/07/2016		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No