

# A trial of 'cognitive remediation therapy' to improve thinking skills and everyday functioning for people with bipolar disorder

<b>Submission date</b> 10/12/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 14/12/2021	<b>Overall study status</b> Ongoing	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 16/06/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Bipolar disorder (BD) is a common, serious condition. Episodes affect mood and energy, fluctuating between very low (depression), high (mania) or a mixture of these (mixed). Effects on work, relationships and quality of life can be devastating, adversely impacting people with BD, those close to them, health and economic systems. The World Health Organisation state that BD is second only to brain injury in the impact it has on ability to work. Disability for many people with BD is caused by "cognitive impairment" -difficulties with thinking skills such as recalling information, attention and planning. Cognitive impairments are a major concern for people with BD even when not in episodes. Treatment currently focuses on short-term mood but these ongoing, disabling difficulties are often overlooked in healthcare, despite directly affecting abilities to function well in daily life. They also affect long-term recovery prospects.

For people with schizophrenia (who have similar cognitive impairments), a psychological therapy – cognitive remediation (CRT) – provides meaningful, longlasting benefits, such that it is now recommended internationally. Recent small trials suggest that CRT could improve the lives of people with BD. In our study with 60 participants, CRT improved cognition and function with benefits remaining 3 months after therapy. The existing studies are promising, but not big enough to confidently show whether CRT is an effective treatment for BD, so we are doing a larger study aiming to show whether CRT is effective at improving everyday and cognitive functioning and indicate what factors are causing any benefits found.

### Who can participate?

Adults aged 18 - 65 years with a confirmed diagnosis of bipolar disorder type I or II.

### What does the study involve?

We will recruit 250 people from a range of sources (e.g. health services and places in the community) and randomly allocate them to receive 12 weeks of either evidence-based CRT (125 people) or continue usual care without CRT (125 people). We will test their cognitive skills and everyday functioning before and after the 12-week program, then 3 months later. We will compare these two groups to see whether CRT is better than usual treatment at improving

everyday (including work-related) and cognitive functioning. To explore what makes the therapy effective, we will also test whether CRT affects peoples' knowledge about their cognitive skills, stress hormones and mood instability and whether these changes relate to improved functioning. This may help increase future benefits that CRT could provide.

What are the possible benefits and risks of participating?

We do not yet know for certain whether CRT is beneficial for people with bipolar disorder, but participants may find the therapy itself beneficial if they are randomised to receive it. For everyone taking part, it is possible that the cognitive measures taken at research visits will be to some extent frustrating (if they feel that they are not performing well) and/or helpful in identifying their cognitive strengths and weaknesses

Where is the study run from?

King's College London (UK)

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

December 2021 to May 2026

Public involvement & dissemination

We are working with the charity Bipolar UK and people with BD to help ensure we research CRT in ways most relevant to those affected. The study proposal has been reviewed by people affected by BD and their feedback influenced which measure (functioning) we chose as the main outcome of the trial, other details of the design, and improvements to our language use. Focus groups are also taking place to finalise details and named service users will contribute to study documents as well be in trial steering groups. Our work so far with people affected by BD confirms a keenness for psychological therapies and wish to improve their functioning at work, socially and cognitively (all core parts of our 'everyday functioning' outcome measure). Service users will be involved in dissemination via charities and support groups; results will be shared with participants, public media channels, scientific meetings and journals (with articles accessible to all).

Who is funding the study?

National Institute for Health Research (NIHR) (UK).

Who is the main contact?

cribstudy@kcl.ac.uk

## Contact information

**Type(s)**

Scientific

**Contact name**

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Public, Principal investigator

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

310423

### **ClinicalTrials.gov (NCT)**

Nil known

### **Protocol serial number**

IRAS 310423, NIHR132619

## **Study information**

### **Scientific Title**

Cognitive Remediation in Bipolar (CRiB2): a randomised trial assessing efficacy and mechanisms of cognitive remediation therapy compared with usual care

### **Acronym**

CRiB2

### **Study objectives**

An improvement in (cognitive and daily) functioning for people randomised to Cognitive Remediation Therapy in addition to Usual Care, compared with people randomised to Usual Care alone.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 14/04/2022, London - Bromley Research Ethics Committee (Temple Quay House, 2 The Square, Temple Quay, Bristol BS1 6PN; +44 (0)207 104 8118; bromley.rec@hra.nhs.uk), ref: 22/LO/0210

### **Study design**

Multisite single-blind (outcome assessor) randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

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

Bipolar disorder

### **Interventions**

Participants are randomly allocated to one of two groups.

Intervention group: Cognitive remediation therapy (CRT) alongside their usual treatment. This involves attending 1-3 CRT sessions per week (estimated 1 hour each) for 12 weeks, in addition to individual computerised exercise practice when convenient.

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

Participants will be block randomised in a 1:1 ratio using a web-based randomisation system which is secure and ensures the allocation sequence will be concealed from researchers.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

Everyday functioning, assessed using the Functioning Assessment Short Test. This is measured at baseline, 13 and 25 weeks with the primary outcome timepoint as 25 weeks.

### **Key secondary outcome(s)**

1. Everyday functioning assessed using the FAST at week 13.
2. Cognition (assessed via individual cognitive domains and global cognitive function score) at weeks 13 and 25. NB this is comprised of 8 individual cognitive tests in addition to global score).
3. Participant-rated cognitive complaints (assessed using the Perceived Deficits Questionnaire [PDQ]) at weeks 13 and 25.
4. Participant-defined goal attainment (assessed using the Goal Attainment Scale [GAS]) at

weeks 13 and 25.

5. Sleep quality (assessed using the Pittsburgh Sleep Quality Index [PSQI]) at weeks 13 and 25.
6. Health-related quality of life (assessed using the EuroQoL-5 Dimensions [EQ5D]) at weeks 13 and 25.
7. Depressive symptoms (assessed using the Hamilton Depression Rating Scale [HAMD]) at weeks 13 and 25.
8. Manic symptoms (assessed using the Young Mania Rating Scale [YMRS]) at weeks 13 and 25.

Mechanistic outcomes:

1. Cortisol secretion (week 13, adjusted for week 0) in association with global cognition (at week 25) between CR+TAU vs TAU groups.
2. Global cognition (as defined above) (at week 13, adjusted for week 0) in association with FAST (at week 25) between CR+TAU vs TAU groups.
3. Metacognitive skills (MAI/Torres' measures) (at week 13, adjusted for week 0) in association with FAST (at week 25) between CR+TAU vs TAU groups.
4. Affect fluctuation (PANAS) (at week 13, adjusted for week 0) in association with FAST (at week 25) between CR+TAU vs TAU groups.

### **Completion date**

31/05/2026

## **Eligibility**

### **Key inclusion criteria**

1. Have a confirmed diagnosis of bipolar disorder type I or II.
2. Be aged between 18 and 65 years.
3. Be euthymic (not in a mood episode) for at least 1 month.
4. Be able to use a computerised device (e.g., computer / smartphone).

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Upper age limit**

65 years

### **Sex**

All

### **Key exclusion criteria**

Current participant exclusion criteria as of 04/05/2022:

1. Substance use diagnosis (abuse or dependence).

2. Risk of suicide.
3. Impairing neurological disorder or MCI.
4. Previous cognitive remediation therapy.
5. Unable to communicate fluently in English.
6. Intellectual disability.
7. Currently undergoing psychological therapy or planning imminent treatment change.
8. Non-provision of UK healthcare professional contact.
9. Unable to travel to one of the research sites on a regular basis over 25 weeks.
10. Unable to provide informed consent to participate.

Previous participant exclusion criteria:

1. Substance use diagnosis (abuse or dependence).
2. Risk of suicide.
3. Impairing neurological disorder or MCI.
4. Previous cognitive remediation therapy.
5. Unable to communicate fluently in English.
6. Intellectual disability.
7. Currently undergoing psychological therapy or planning imminent treatment change.
8. Non-provision of UK healthcare professional contact.
9. Unable to provide informed consent to participate.

**Date of first enrolment**

01/04/2022

**Date of final enrolment**

30/06/2025

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**King's College London**

South London & Maudsley NHS Trust

King's Clinical Research Facility

Denmark Hill

London

United Kingdom

SE5 9RS

**Study participating centre**

**Birmingham University**

Birmingham & Solihull NHS Trust

Birmingham

United Kingdom  
B13 8QY

**Study participating centre**

**Oxford University**  
Oxford Clinical Research Facility  
Warneford Hospital  
Oxford  
United Kingdom  
OX3 7JX

**Study participating centre**

**Newcastle University**  
Wolfson Research Centre  
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust  
Newcastle  
United Kingdom  
NE4 5PL

## Sponsor information

**Organisation**

King's College London

**ROR**

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

## Funder(s)

**Funder type**

Government

**Funder Name**

National Institute for Health and Care 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

Requests for data sharing will be considered by the Chief Investigator on a case by case basis.  
(dimosthenis.tsapekos@kcl.ac.uk)

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		15/11/2023	16/11/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes