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

Submission date
10/12/2021

Recruitment status
No longer recruiting

Registration date
14/12/2021

Overall study status
Ongoing

Last Edited
16/06/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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

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Scientific

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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
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Study participating centre
Newcastle University
Wolfson Research Centre
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
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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?
Protocol article		15/11/2023	16/11/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes