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Cognitive remediation therapy in bipolar disorder

Submission date
03/02/2016

Recruitment status
No longer recruiting

Registration date
03/02/2016

Overall study status
Completed

Last Edited
10/03/2023

Condition category
Mental and Behavioural Disorders

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/04/2015

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60; Description:
One group only, in the UK. Of the 60 participants, 30 will be randomised to CRT intervention and 3(

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
England

United Kingdom

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
Landor Road
Clapham
London
United Kingdom
SW9 9NU

Sponsor information

Organisation
King's College London (UK)

Sponsor details
Strand
London

England
United Kingdom
WC2R 2LS

Sponsor type
University/education

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

Publication and dissemination plan
Planned publication of a study protocol, a paper detailing the primary findings according the study outcomes and a third paper with supplementary results including the prediction of treatment success. All publications will be in indexed, high quality journals and will be available open access.

Intention to publish date
01/07/2020

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?
Protocol article	protocol	29/07/2016		Yes	No
Results article	results	01/03/2021	26/06/2020	Yes	No
Results article	Exploratory study	01/07/2021	10/03/2023	Yes	No
HRA research summary			28/06/2023	No	No