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A trial of a new psychological intervention of cognitive behaviour therapy for young people with distressing mood swings

Submission date
11/01/2023

Recruitment status
No longer recruiting

Registration date
25/01/2023

Overall study status
Ongoing

Last Edited
07/10/2025

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) affects around 1-3% of the population. 1.14 million people met the criteria for BD in 2007 and this is expected to rise to 1.23 million by 2026. The World Health Organisation states BD is one of the main reasons for loss of life and health in 15–44-year-olds, and BD increases the rate of suicide above the general population by 20-30 times. It is poorly recognised, especially in the early stages. People often experience misdiagnosis which causes frustration and disengagement with services. This also leads to incorrect treatment which can make peoples' difficulties worse. BD also has financial costs; the approximate cost of BD in the UK for 2007 was £5.2 billion and this is likely to rise to £8.2 billion per year by 2026.

People who experience symptoms of high and low mood and meet the criteria for Bipolar at Risk (BAR) are at high risk of developing a full episode of BD. If these individuals are identified early, then interventions aimed at reducing these symptoms and associated distress may reduce the chance of a future full-blown episode of BD. Early intervention for psychosis services have been successfully set up throughout England. Extending early intervention to other mental health problems such as BD would be a major step forward in preventing long-term problems, distress, disability and financial costs.

The importance of developing interventions with a focus on health promotion and prevention has long been recognised. A pilot study was carried out to see whether a psychological therapy (cognitive behavioural therapy, CBT) can be given to individuals who meet the criteria for BAR, and whether it could be a potentially useful treatment. It showed that CBT (CBT-BAR) is an acceptable (as shown by feedback from people who took part) and feasible treatment option (as shown by people agreeing to take part and attending the therapy sessions) for people meeting BAR criteria. The study also had promising findings such as improved mood and functioning. Those who took part spoke positively about their experiences and the impact it had on their life. The researchers will now replicate this study to understand if this therapy works in a larger group of people. The aim of this study is to conduct a large randomized controlled trial (RCT) comparing CBT-BAR to the usual treatment for individuals meeting BAR criteria. Half of the people who agree to take part will be offered CBT and half will not be offered CBT, but their usual treatment will not be affected. This will allow us to see whether CBT is an effective and helpful treatment option for this group. This study would also help to show whether changes

which are targeted through CBT-BAR make a difference in peoples' experiences of distressing mood swings and other outcomes important in the lives of these young people.

Who can participate?
Young people who are aged between 16-25 years and who meet the bipolar at-risk criteria will be eligible to take part. The bipolar at-risk criteria include three different groups of mood swing experiences. The first group are young people who experience elevated mood that lasts at least two consecutive days. The second group are young people who experience hours of elevated mood as well as periods of low mood. The third group are young people who experience episodes of low mood and have a first-degree relative with a diagnosis of bipolar disorder.

What does the study involve?
Young people referred to the study will meet with a researcher and complete a 'detailed assessment' to check their experiences meet the criteria for the study, as well as complete different questionnaires. If the person is confirmed as suitable for the study, they will be randomly selected to be offered the CBT-BAR intervention plus their treatment as usual, or they will remain as receiving their treatment as usual alone. If the person is offered the CBT-BAR intervention, they will meet with a clinical psychologist or CBT therapist for up to 26 sessions. They will then be seen by the researcher for follow-up appointments planned for 4, 6 and 12 months after their initial appointment.

What are the possible benefits and risks of participating?
The initial assessment may help to highlight any problems the young person is experiencing. If appropriate, the research team can signpost to other services that may be helpful. For 50% of people in the study, it is hoped that being randomly allocated to receive the CBT-BAR intervention will be helpful. It is possible that the CBT-BAR intervention will improve mental health difficulties, however, this cannot be guaranteed. The information from this study may help improve the treatment of people who have problems related to concerns about mood swings. For all participants, there will be regular appointments throughout the year with a research assistant. Participants from the previous BART study reported that these appointments were helpful. It is also possible that talking about some of these issues during the assessments may be upsetting. Participants will have the opportunity to discuss any concerns they have with the researcher and are free to withdraw from the study at any point without giving a reason. This decision will not affect any care they receive now or in the future.

Where is the study run from?
The study is taking place in five locations around the UK: Manchester, Lancashire, Sheffield, Birmingham, and Norfolk & Suffolk

When is the study starting and how long is it expected to run for?
December 2020 to July 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) Efficacy and Mechanism Evaluation Programme (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
316335

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 54408, IRAS 316335

Study information

Scientific Title
Cognitive behavioural therapy in comparison to treatment as usual in young adults at high risk of developing bipolar disorder (Bipolar At Risk): a randomised controlled trial to investigate the efficacy of a treatment approach targeted at key appraisal change

Acronym
BART II

Study objectives
Efficacy Hypotheses
1. Cognitive Behavioural Therapy for Bipolar At Risk (CBT_BAR) + Treatment As Usual (TAU) will lead to improvement in mood swings (SCID-5 + PSR's (SCID LIFE)) compared to TAU alone at:
1.1. End of treatment (27-week follow-up)
1.2. Follow-up (52-week follow-up)
2. CBTBAR + TAU will reduce the likelihood of transition to BD in comparison to TAU alone over a 52-week follow-up time period.
3. CBTBAR + TAU will lead to improved functioning and quality of life compared to TAU alone over a 52-week follow-up time period.

Mechanistic Hypotheses
1. CBTBAR + TAU will reduce extreme positive and negative appraisals of internal states (HAPPI) and subsequent behaviours used to control mood (BC) at 27 weeks
2. The mechanism by which CBTBAR causes improvement in mood swings (SCID-5 + PSR's (SCID LIFE)) is due to the reduction of extreme positive and negative appraisals of internal states (HAPPI) which in turn improves subsequent behaviours used to control mood (BC) and then internal states (ISS)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/12/2022, North West – Greater Manchester West Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8379, +44 (0)2071048109; gmwest.rec@hra.nhs.uk), ref: 22/NW/0355

Study design
Randomized; Interventional; Design type: Treatment, Prevention, Psychological & Behavioural

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bipolar disorder

Interventions

This trial will be a multicentre, rater-blinded randomised control trial with two parallel arms. It will compare a psychological intervention (Cognitive Behavioural Therapy for Bipolar At Risk [CBT_BAR]) + Treatment As Usual (TAU) (treatment condition) to TAU alone (control condition).

Outcome and mediational variables will be collected at baseline, 17 weeks, 27 weeks (after therapy cessation), and 52 weeks. Up to 26 individual weekly therapy sessions of up to 60 mins will be offered within a 26-week treatment window. Participants will be randomized to one of two trial arms. Randomization will be independent and concealed, using permuted stratified blocks where site (5-levels) and BAR group (3-levels) are the stratification factors. It will be conducted via a web-based system conducted within York Clinical Trials Unit (CTU).

The intervention will be a novel Cognitive Behaviour Therapy (called CBT_BAR). The trial therapist will be delivering CBT_BAR in a 26-week treatment envelope allowing up to 26 sessions as follows:
1. Mood continuum work
2. Problem list generation
3. Goal setting
4. Idiosyncratic formulation (maintenance and longitudinal) derived from model
5. In-session measurement of appraisals and behaviour
6. Cognitive strategies to target key appraisals of mood: advantages/disadvantages; developing alternative explanations; evidential analysis; surveys; cognitive processes; beliefs of self, world and other.
7. Behavioural strategies: behavioural experiments; behavioural analysis including intended mood management

Sessions will be offered face-to-face, but we will also offer flexible appointments via video calls (using NHS trust-approved platforms such as TEAMS). Flexibility was a key theme found in the qualitative work conducted with the participants from the original BART trial conducted in 2015-2018.

The control condition is treatment as usual (TAU), consisting of multi-disciplinary care delivered by a range of health professionals and services such as GPs, mental health services (e.g. primary care psychology), and university counselling services.

Qualitative interviews will be conducted to learn the participants' perceptions of how CBT_BAR affects psychologically driven appraisals and subsequent behaviours that control mood in the pathway to high and low mood states. In addition, interviews with key stakeholders will be undertaken to learn about the acceptability of this intervention in NHS service provision.

Intervention Type
Behavioural

Primary outcome(s)
Mood swing symptom severity averaged over the prior 4 weeks, measured by the SCID-5 + Psychiatric Status Ratings/PSRs (SCID Longitudinal Follow-Up Evaluation (LIFE) at the 27-week timepoint

Key secondary outcome(s))
1. Appraisals of and responses to mood to determine the impact of CBT_BAR, measured by the Internal States Scale, Hypomanic Positive Predictions Inventory, and Behaviours Checklist at baseline, 17 weeks, 27 weeks, and 52 weeks

2. Transition to (hypo)mania, % of time in subthreshold symptoms, and time in symptoms, measured by the SCID LIFE (SCID-5 assessment, Modules A, B, C, & D + Psychiatric Rating Scores), the Young Mania Rating Scale, the Beck Depression Inventory, and the Altman Self Rating Scale at baseline and the 27-week and 52-week timepoints
3. Health utility and healthcare costs will be measured by the Service Use Interview, the EQ-5D, and the Recovering Quality of Life each measured at baseline, 27- and 52-week timepoints
4. Functioning and quality of life will be assessed by the Global Assessment of Functioning, Social and Occupational Functioning Assessment Scale, and the World Health Quality of Life at the baseline, 27- and 52-week timepoints
5. Sleep and related sleep appraisals will be assessed by the Pittsburgh Sleep Quality Index and the Positive and Negative Sleep Appraisal Measure at baseline, 27-week and 52- week timepoints
6. Metacognitive beliefs will be assessed by the Metacognitions Questionnaire and the Desire Thinking Questionnaire at baseline, 27-week, and 52-week timepoints
7. Response style and schema will be assessed by the Response Style Questionnaire and the Brief Core Schema Scale at baseline, 27-week and 52-week timepoints
8. Substance use, anxiety diagnoses, feeding & eating disorder, trauma & stress-related diagnoses, body dysmorphic disorders, and sleep/wake disorders will be assessed by the relevant SCID-5 module at baseline only

Completion date
31/07/2026

Eligibility

Key inclusion criteria
The study population are young people meeting BAR criteria. The inclusion criteria are:
1. 16-25 years old
2. Meet criteria for one of the following groups in the last 12 months (as assessed by the SCID-5):
2.1. Group I: Sub-threshold mania.
For at least 2 consecutive days but less than 7 days: period of abnormally and persistently elevated, expansive or irritable mood + at least 2 criteria from the list (>=3 for irritable mood):
2.1.1. Inflated self--esteem/grandiosity
2.1.2. Decreased need for sleep
2.1.3. More talkative than usual
2.1.4. Flight of ideas/racing thoughts
2.1.5. Distractibility
2.1.6. Increase goal-directed activity or psychomotor agitation
2.1.7. Excessive involvement in activities that have a high potential for painful consequences
2.2. Group II: Depression + Cyclothymic features:
Depression (for at least 1 week): depressed mood/loss of interest or please + two criteria from the list:
2.2.1. Significant weight loss
2.2.2. Insomnia or hypermania nearly every day
2.2.3. Psychomotor retardation/agitation
2.2.4. Fatigue/loss of energy
2.2.5. Feelings of worthlessness/excessive or inappropriate guilt
2.2.6. Diminished ability to think or concentrate
2.2.7. Recurrent thoughts of death/suicidal ideation
PLUS
Cyclothymic features: numerous episodes with sub-threshold manic symptoms not meeting Group 1 criteria: subthreshold mania as defined in Group 1 for 4 hours within a 24-hour period

and at least 4 cumulative lifetime days in the past 12 months.
2.3. Group III: Depression + genetic risk:
Depression (See Group 2)
PLUS
Genetic risk: first degree relative with BD
3. Help seeking
4. Provision of written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Upper age limit
25 years

Sex
All

Total final enrolment
337

Key exclusion criteria
1. History of a treated/untreated manic episode or psychosis of 1-week duration or longer
2. Treatment with a mood stabiliser for longer than 6 weeks or antipsychotic for 3 weeks (that evidences exclusion on point a or at the time of the assessment whereby at-risk status cannot be confirmed)
3. Organic brain disorder
4. Unable to complete assessments due to language barriers
5. Inpatient/acute psychiatric care needed
6. Primary substance abuse/dependency

Date of first enrolment
01/02/2023

Date of final enrolment
31/07/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Prestwich Hospital
Bury New Road
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Manchester
United Kingdom
M25 3BL

Study participating centre
Lancashire & South Cumbria NHS Foundation Trust
Sceptre Point
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PR5 6AW

Study participating centre
Norfolk and Suffolk NHS Foundation Trust
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NR6 5BE

Study participating centre
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S4 7QQ

Study participating centre
Birmingham Women's and Children's NHS Foundation Trust
Steelhouse Lane
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Sponsor information

Organisation
Greater Manchester Mental Health NHS Foundation Trust

ROR
https://ror.org/05sb89p83

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR132622

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/07/2025	02/07/2025	Yes	No
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes