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Randomised controlled trial investigating therapy for bipolar inter-episode symptoms

Submission date
04/03/2024

Recruitment status
No longer recruiting

Registration date
13/03/2024

Overall study status
Ongoing

Last Edited
11/07/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Some people with bipolar disorder experience ongoing low mood or mood swings outside of full episodes of depression or mania. This might be associated with a sense of never feeling properly "well", or of not having extended periods of stable mood. Most of the research that has looked at psychological therapies for people with bipolar disorder has focussed on helping people recover from periods of major depression, or on reducing the chance of having another major episode. These are important issues to address, however, we do not yet have a therapy that is specifically designed to address ongoing symptoms. Researchers have been working on developing such a therapy. The long-term aim is to help the NHS to offer a treatment that can support people with bipolar disorder who would particularly like support with persisting low mood or mood swings.
This study is to test out aspects of the therapy and of the research processes in preparation for being able to run a large clinical trial in future. This study cannot give the final answer on whether the therapy works in general: a larger study is needed for this. However, this small study is a necessary step towards a bigger trial.

Who can participate?
People with ongoing symptoms of bipolar disorder between major episodes

What does the study involve?
The study involves either receiving the new therapy or continuing with usual care without receiving the new therapy. This is decided at random and there is a 50% chance of receiving the therapy. Throughout the study there are several questionnaires to complete at different time points over 12 months.

What are the possible benefits and risks of participating?
Behavioural therapies for people with depression and for people with emotional instability have been found to be beneficial overall, and early-stage studies with people with bipolar disorder suggest that this may be a helpful approach.
The researchers do not anticipate that this therapy programme will place participants at any more risk than they would face if they attended other therapeutic programmes.

Where is the study run from?
Exeter Clinical Trials Unit at the University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
September 2023 to November 2026

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

Who is the main contact?
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Contact information

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Scientific, Principal investigator

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
335983

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 335983, CPMS 60510

Study information

Scientific Title
The clinical and cost-effectiveness of behavioural therapy for interepisode bipolar symptoms (STABILISE): a feasibility study

Acronym
STABILISE

Study objectives
Assessment of the acceptability and feasibility of a future trial.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/01/2024, East of England - Cambridge East Research Ethics Committee (2 Redman Place, London, EC20 1JQ, United Kingdom; +44 (0)2071048181; CambridgeEast.REC@hra.nhs.uk), ref: 24/EE/0018

Study design
Two-arm randomized parallel controlled feasibility trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
This is a feasibility study with two arms: usual care + the new therapy, and usual care only. 60 participants will be randomised to these two arms, with half receiving each.

As this is a feasibility trial the researchers will be using data from the trial to characterise usual care to refine their understanding of this for a future definitive trial. As such we do not place any restrictions on what people receive as part of usual care. This could therefore include the full range of NHS and private/third sector health assessments and interventions available to the person. Similarly, the researchers do not mandate any healthcare assessment to be part of usual care (i.e. there is not a stated minimum set of components).

The intervention therapy consists of up to 20 individual, hour-long therapy sessions (plus up to two initial assessment sessions) of behavioural therapy, delivered over up to 7 months (30 weeks). This is followed by a period of consolidation whereby patients can opt to see the therapist up to 3 times up until 12 months after starting therapy.

Participants will complete measures of clinical symptoms, quality of life/sense of personal recovery and use of healthcare services at four time points: study intake, 14 weeks after intake, 30 weeks after intake, and 52 weeks after intake. They will also complete additional measures at some of these time points. Further details are given below.

Measures:
Demographic assessment at baseline only:
1. Demographic questionnaire: age, gender, ethnicity, relationship status, highest level of education, perceived financial status, currently open to secondary care services.

Measures to assess eligibility:
The following measures will be completed at intake to assess participant eligibility.
1. Structured clinical interview for DSM-V (SCID-5) – at baseline only. The Hamilton Depression Rating Scale (HAM-D: Hamilton, 1960) will be used with participants who meet the criteria for a current depressive episode to establish severity (those scoring in the severe range of >=24 will not be eligible). The International Classification of Diseases, 11th revision (ICD-11) will be used to determine the presence or absence of current substance dependence.
2. Patient Health Questionnaire – 9 (PHQ-9)
3. Affective Lability Scales - short version (ALS)

Clinical outcome measures (completed at baseline, 14-, 30- and 52-week follow-up):
1. PHQ-9
2. ALS
3. Bech-Rafaelsen Mania Scale (BRMS)
4. Brief Quality of Life in Bipolar Disorder (QoLBD)
5. General Anxiety Disorder Assessment – 7 (GAD-7)
6. Bipolar Recovery Questionnaire (BRQ)
7. Life chart self-report – self-report of number and duration of depressive and manic episodes in the period since the last assessment (completed at 14, 30 and 52-week follow-up points only)
8. Health Economics Questionnaire (HEQ)
9. EQ-5D-5L

Process measures (completed at baseline, 14 and 30 week follow-up):
1. Positive and Negative Urgency Scales (PU & NU)
2. Behavioural Activation in Depression Scale – Short Form (BADS-SF)
3. Momentary Assessment Block (MAB: completed at baseline, 14 and 30-week follow-up points). Participants will be invited to report on their current mood and activity 5 times per day for 10 days via a purpose-built
web application (momentary assessment block). These momentary assessment blocks will take place on three occasions: for 10 days following the intake assessment, for 10 days at 14 weeks post-randomisation, and for 10 days following the 30-week follow-up point.
4. Altman Scale for Rating Mania (ASRM)
5. Beck Depression Inventory (BDI)

Qualitative interview:
At 30 weeks (patient participants) and at the end of the trial (therapists) there will be audio-recorded qualitative interviews of approximately 60 minutes conducted by one of the research team exploring experiences of the therapy.

Intervention Type
Behavioural

Primary outcome(s)
1. Average recruitment rate recorded as the number of eligible participants recruited per site over 15 months to assess the feasibility of a future trial
2. Completion of the 30-week follow-up point

Key secondary outcome(s))
Clinical outcome measures (completed at baseline, 14, 30 and 52-week follow-up)
1. Depression symptom severity measured using the Patient Health Questionnaire – 9 (PHQ-9)
2. The extent to which mood tends to fluctuate measured using the Affective Lability Scales (ALS)
3. Level of current mania symptoms measured using the Bech-Rafaelsen Mania Scale
4. Disorder-specific quality of life measured using Brief Quality of Life in Bipolar Disorder (QoLBD)
5. Anxiety symptoms measured using the General Anxiety Disorder Assessment – 7 (GAD-7)
6. Sense of personal recovery measured using the Bipolar Recovery Questionnaire (BRQ)
7. Life chart self-report – self-report of number and duration of depressive and manic episodes in the period since the last assessment (completed at 14, 30 and 52-week follow-up points only)
8. Health economic variables (employment, health service use, ability to perform activities of daily living) measured using the Health Economics Questionnaire (HEQ) over the past 6 months / since last contact
9. Health-related quality of life measured using EQ-5D-5L

Completion date
30/11/2026

Eligibility

Key inclusion criteria
Participants will be adults who:
1. Meet research diagnostic criteria for Bipolar I or II Disorder, Other Specified Bipolar Disorder or Cyclothymic Disorder
2. Do not meet the criteria for a manic or severe depressive episode
3. Have IEBS, defined as at least mild depressive symptoms (Patient Health Questionnaire [PHQ9] >=5) or above-average bipolar mood instability defined as >=1.3 on the brief Affective Lability Scale (ALS) depression-elation scale
4. Are willing to engage in psychological work addressing IEBS or its impact on functioning
5. Sufficient English to complete questionnaires without translation
6. Have completed the intake measures
7. Are registered with a General Practice within the study site catchment area

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Current substance dependence according to ICD-11 criteria (as this may interfere with the ability to engage in and use therapy; current substance abuse is not an exclusion criterion).
2. Risk of harm to self or others that cannot be safely managed in a community outpatient setting.
3. Currently engaged in another psychological therapy for bipolar disorder.
4. Participant anticipates they will be unable to regularly attend therapy sessions within the site area (e.g. planning to move out of the study area, work commitments prevent regular attendance, lengthy period of travel not mitigated by access to online therapy sessions).

Date of first enrolment
01/04/2024

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Accept Clinic (university of Exeter)
Mood Disorders Cent, School of Psyc
University of Exeter, Perry Road
Washington Singer Building
Exeter
United Kingdom
EX4 4QG

Study participating centre

Avon and Wiltshire Mental Health Partnership NHS Trust
Bath NHS House
Newbridge Hill
Bath
United Kingdom
BA1 3QE

Study participating centre
Devon Partnership NHS Trust
Wonford House Hospital
Dryden Road
Exeter
United Kingdom
EX2 5AF

Sponsor information

Organisation
University of Exeter

ROR
https://ror.org/03yghzc09

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

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. All trial data excluding personally identifiable information will be made available indefinitely. Consent from participants will be obtained for data to be stored for the purposes of other ethically approved research in the future and that data will be shared anonymously.

IPD sharing plan summary

Stored in publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	version 1.0	10/07/2025	11/07/2025	Yes	No
Statistical Analysis Plan			17/02/2025	No	No