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Psychological therapy for ongoing symptoms of bipolar disorder

Submission date
31/01/2023

Recruitment status
No longer recruiting

Registration date
01/02/2023

Overall study status
Completed

Last Edited
06/01/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Bipolar spectrum disorders typically involve periods of depression and periods of very high energy and mood (hypomania or mania). Bipolar disorders are common, affecting around 1 in 20 people at some point in their lifetime. They can be very distressing and disruptive to the people who experience them, and for friends and relatives. Many people with these conditions have mood issues outside episodes of depression or mania. Often these issues include ongoing low mood, and/or frequent swings in mood or emotions. These are sometimes called “inter-episode bipolar symptoms”.
There are psychological (talking) therapies designed to help people with bipolar disorders, but these tend to be aimed at preventing the person from becoming really unwell, in other words from having a relapse of depression or mania, or they are aimed at helping people recover from a period of depression. There is no universally accepted talking therapy for helping people who have ongoing low mood or mood swings in between full episodes, despite the fact that these are common and distressing, and can make life more difficult.
The aim of this research programme is to take the first step in developing such a talking therapy. Along with people with lived experience of bipolar disorders the researchers will integrate and adapt two similar talking therapies they have previously developed for mood swings and for bipolar depression. After developing the new therapy it will be tested initially in a small number of people, to help improve it based on feedback from the patients and therapists. The overall goal is to develop a therapy that is promising in terms of being ready to test in a clinical trial.

Who can participate?
Adults with bipolar disorder or cyclothymic disorder who have ongoing low or unstable mood outside of full episodes of mania or depression

What does the study involve?
The study involves an assessment meeting with a researcher to see if the study is a good fit. If so, the participant is asked to complete some questionnaires at regular intervals and invited to attend one-to-one psychological therapy sessions.

What are the possible benefits and risks of participating?
The benefits include the potential to have psychological therapy. The risks include receiving a

therapy that has not been fully tested in people with ongoing bipolar symptoms (although it has been used extensively with other patient groups) and being asked questions about potentially sensitive or emotional topics such as past mental health, which could be distressing.

Where is the study run from?
The University of Exeter (UK)

When is the study starting and how long is it expected to run for?
January 2021 to December 2025

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

Who is the main contact?
Dr Kim Wright, K.A.Wright@ex.ac.uk

Contact information

Type(s)
Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
320627

Central Portfolio Management System (CPMS)
54522

National Institute for Health and Care Research (NIHR)
302220

Study information

Scientific Title
Behavioural therapy for inter-episode bipolar symptoms: a multiple baseline case series evaluation

Acronym
STABILISE

Study objectives
Aims:
1. To allow initial evaluation of intervention safety, feasibility and acceptability
2. To investigate whether the pattern of change in symptoms is consistent with the potential of the intervention to deliver benefit
3. To refine the therapy protocol and procedures for training and supervising therapists
4. To develop an initial therapy competence and adherence measure

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/12/2022, South West – Central Bristol Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, UK; +44 (0)207 104 8029, centralbristol.rec@hra.nhs.uk), ref: 22/SW/0165

Primary study design
Interventional

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

Study type(s)
Treatment

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

Interventions
The study will involve participants being recruited in two waves or cohorts (6 in each) to allow iteration of the therapy protocol.

In a multiple baseline case series, individuals in the study are randomly allocated to baseline periods of different lengths (in other words the timing of the start of treatment is staggered across participants). This design increases the likelihood that symptom change which onsets following the start of treatment is due to the effects of treatment rather than to non-treatment related factors such as measurement repetition effects, or spontaneous recovery over time. In the current study, following guidelines on the design of multiple baseline ABA case series (Levin & Ferron, 2021, Tate & Perdices, 2018), the researchers will randomize participants to between 3 and 5 weeks of baseline measurement (allowing a minimum of three weekly measurements during the baseline phase, and three baseline lengths that participants can be randomized to).

Participants will complete a set of outcome measures at baseline, pre-therapy and 7 months after the start of therapy, as well a smaller set of weekly measures.

All participants will be offered therapy.

Procedure:
Following initial contact with the research team, and having been sent the Participant Information Sheet (email or post), participants will attend an intake assessment interview lasting approximately 90 minutes. In this interview the study will be discussed and any questions the participant has will be addressed. Those giving written informed consent to take part will then complete a demographic information form, will complete a research diagnostic interview, will complete measures of depression and mood lability (PHQ-9, depression elation subscale of the ALS), and will be asked additional questions to establish whether the inclusion and exclusion criteria are met. Participants eligible and willing to continue will complete the other self-report measures (GAD7, ASRM, QoLBD, remaining ALS items and BRQ).

Where possible the intake assessment will be conducted face to face (either at the research site or at the participant's home or another mutually agreed confidential space) however if participants have a strong preference for the assessment to be conducted remotely this will be accommodated. Written consent will be obtained prior to the meeting via post following a brief telephone or online conversation with the researcher to allow the participant to ask questions about the study and have it explained to them. The intake assessment will not be conducted unless written informed consent has been given. Self-report measures at intake will be completed online (using a bespoke data collection platform) or using pen and paper if participants would prefer not to complete them online.

Participants will then be randomized by a researcher independent of the study to one of three wait periods (3, 4, or 5 weeks) and will complete the first momentary assessment block. Starting 1 week after the baseline assessment participants will complete weekly symptom measures (PHQ-9, ASRM and ALS depression-elation questions) over the baseline period, therapy period and for 3 weeks post-therapy. These will be completed online where possible or posted in a batch at the start of the waiting period if participants decline online measures. Reminders to complete the measures are built into the data collection system and participants will be made aware of this. They will also agree with the researchers on how the team should attempt to reach out to them if they do not complete measures, including the option to nominate a friend or family member as a point of contact.

Within 1 week of the initial assessment participants will be contacted by the researcher to check on their wellbeing, and also to check if they have any questions about measure completion and to inform them of the wait length until therapy starts.

After reaching the end of their allocated wait period, participants will complete the GAD7, ASRM, BQoLBD, additional ALS items and BRQ. At this point they will speak with the researcher to check that they are satisfied with the arrangements for commencing therapy. Therapy will then commence on an approximately weekly basis. At the end of therapy participants will complete 3 weeks of post-therapy monitoring during which time they will continue to complete the weekly measures and will be invited to take part in a semi-structured, audio-recorded interview about their experiences of the study and the therapy. They will also complete the second momentary assessment block. At 7 months after their pre-therapy assessment they will be invited to complete the battery of measures used at baseline and pre-treatment for a final time.

After attending any "booster" sessions (if they choose to do so) participants will be asked to complete a brief feedback questionnaire about this aspect of the therapy.

Individuals who choose not to continue with the therapy will be assumed to be continuing with the research aspect of the study. If participants opt to discontinue the research element of the study they will not be contacted further by the research team, other than to be sent a brief survey to ascertain their reasons for not taking part if they initially gave their consent for this. If the participant has commenced therapy, for ethical reasons they will be able to continue with the treatment if they opt to.

The end of the study will be defined as the final piece of available data being collected from the final participant.

Intervention Type
Behavioural

Primary outcome(s)
1. Safety will be measured by rates of therapy-related adverse events across the study period, and rates of reliable deterioration on the Patient Health Questionnaire (PHQ), Altman Scale for Rating Mania (ASRM), Affective Lability Scale (ALS), Generalised Anxiety Disorder questionnaire (GAD), Quality of Life in Bipolar Disorder scale (QoL.BD) and Bipolar Recovery Questionnaire (BRQ) at 7 months (30 weeks) follow-up
2. Acceptability will be measured by therapy uptake and completion rates across the study period, and quantitative and qualitative feedback from participants and therapists at the post-therapy point
3. Potential of the intervention to deliver benefit will be measured by rates of reliable, and reliable and clinically significant, change in the Patient Health Questionnaire and the bipolar-depression scale of the Affective Lability Scale, from the baseline period (mean score) to the post-therapy period (mean score)

Key secondary outcome(s)
1. Rates of reliable and reliable and clinically significant change on the following measures: Bipolar Disorder Recovery Questionnaire, Quality of Life in Bipolar Disorder Scale and Generalised Anxiety Disorder assessment scale from pre-therapy to 7-month follow-up
2. Rates of reliable and reliable and clinically significant change on the Altman Scale for Rating Mania from the baseline period to the post-therapy period
3. Group-level change in PHQ, ALS, ASRM, BRQ, QoL.BD, GAD from baseline to 6-month follow-up and pre-therapy to 7-month follow-up
4. Mood instability will be measured (in addition to the ALS) by a visual analogue scale of mood at five timepoints per day for 14 days on two occasions (pre and post therapy) for each participant. This allows for the calculation of mood instability before and after therapy

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Adults in the catchment areas of the study sites who:
1. Meet research diagnostic criteria for Bipolar I or II Disorder, Other Specified Bipolar Disorder or Cyclothymic Disorder
2. Do not meet 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. Have sufficient English to complete research questionnaires without translation
6. Have completed the intake measures

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 Years

Sex
All

Total final enrolment
12

Key exclusion criteria
1. Current substance dependence according to ICD-11 criteria
2. Frequent and serious self-harm that cannot be safely managed in a community outpatient setting
3. Currently engaged in another psychological therapy for bipolar disorder

Date of first enrolment
13/02/2023

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
AccEPT clinic
Henry Wellcome Building for Mood Disorders Research

University of Exeter
Exeter
England
EX4 4QG

Study participating centre
Devon Partnership NHS Trust
Research and Development Team
Wonford House
Barrack Road
Exeter
England
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

Anonymised data (fully anonymous to the recipient) will be available on reasonable request from suitably qualified individuals, subject to any necessary approvals being in place on the part of the recipient and a data-sharing agreement. Participants give consent for sharing of anonymous data on entering the study. Contact for data sharing requests: Dr Kim Wright (K.A. Wright@ex.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/12/2025	06/01/2026	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version 1.1	30/11/2022	01/02/2023	No	No
Protocol file	version 1.2	27/04/2023	27/04/2023	No	No
Statistical Analysis Plan	version 1.2	15/06/2023	27/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes