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A trial of a patient app and care team interface designed to facilitate shared decision making for people with bipolar disorder

Submission date
04/07/2025

Recruitment status
Recruiting

Registration date
14/07/2025

Overall study status
Ongoing

Last Edited
26/09/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] 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 long-term condition characterised by recurrent periods of depression and/or mania, separated by periods of stability. BD is rather common and can profoundly impact the duration and quality of patients' lives. While BD treatment often leads to improvement in patients' conditions, the disorder's nature, coupled with complex treatments, results in estimated medication nonadherence rates of up to 80%, which contributes to higher relapse and hospitalisation rates. In recent years, the concept of shared decision making (SDM) has emerged as a method to encourage collaboration between patient and clinician, thereby making the patient more engaged and more likely to adhere to their treatment regimen. However, the implementation of SDM within routine mental health care has been limited by a lack of high-quality, accessible tools/services. A company, Fora Health, has created a digital platform that aims to address this issue by facilitating ongoing monitoring and communication between patients and doctors. This study seeks to (a) develop a version of this service that is tailored to BD patients, and (b) assess its adoption, usability and effectiveness.

Who can participate?
Patients aged 18+ who are being treated for BD alongside their clinicians.

What does the study involve?
Participants will be randomly allocated 1:1 to one of two conditions. One group will continue treatment as usual (TAU) alongside regular use of the Fora Health platform for 6 months, while the other will undergo TAU without using the platform.

The study will consist of six visits, all conducted remotely (e.g., via Microsoft Teams). These are as follows:
• Screening – eligibility assessment
• Baseline – initial assessments and randomisation
• Weeks 3, 8 and 13 – assessment of BD symptoms and engagement with the platform
• Week 26 –final round of questionnaires/assessments

What are the possible benefits and risks of participating?
Potential Benefits:
Digital tools like Fora Health may offer continuous support between appointments, potentially reducing relapse rates and hospitalisations for people with bipolar disorder.

Previous trials in the U.S. suggest the platform can improve engagement, reduce symptom severity, and lower service use among patients with depression.

Regardless of randomisation, participation may contribute to improved future care. If effective, Fora Health could be integrated into mainstream mental health services for bipolar disorder.

Potential Risks:
Participants may experience mild distress during clinical or mood questionnaires. To mitigate this, participants are briefed beforehand, offered breaks, monitored during sessions, and signposted to appropriate support services. Only essential questions are asked, and sensitive topics are minimised.

The time commitment may be a burden; however, participation requirements are discussed in detail prior to consent. Scheduling is kept flexible, with visit frequency and assessment length limited to what is necessary.

Given the nature of bipolar disorder, mood deterioration is a potential risk. This is addressed by excluding participants with active suicidality, monitoring wellbeing at each visit, and involving their regular healthcare team as necessary. All participants must have ongoing clinical care, and their clinician's agreement is required to ensure safety.

There is a small risk of low engagement or dissatisfaction with the Fora Health platform. However, this tool has previously shown positive outcomes in similar populations.

If a clinician withdraws support during the study, participants may continue to attend study visits as scheduled, although use of Fora Health would cease where applicable.

Only participants who are currently well (not experiencing acute mood episodes) and have the capacity to consent are enrolled. The study team includes experienced clinicians, and researchers are trained in good clinical practice and participant safeguarding.

Where is the study run from?
South London and Maudsley NHS Foundation Trust (SLaM), UK

When is the study starting and how long is it expected to run for?
June 2025 to May 2027

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

Who is the main contact?
Paul Leeks, paul.leeks@kcl.ac.uk

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name
Prof Allan Young

ORCID ID
https://orcid.org/0000-0003-2291-6952

Contact details
King’s College London
PO72, De Crespigny Park,
Denmark Hill
London
United Kingdom
SE5 8AF
+44 (0)2078485895
a.young@imperial.ac.uk

Type(s)
Public

Contact name
Mr Paul Leeks

ORCID ID
https://orcid.org/0000-0002-5005-1629

Contact details
King’s College London
16 De Crespigny Park
Denmark Hill
London
United Kingdom
SE5 8AF
+44 (0)2078485895
paul.leeks@kcl.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
347987

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 69079, NIHR206433

Study information

Scientific Title
A randomised feasibility trial of a patient app and health-record-integrated care team interface to facilitate shared decision making for people with bipolar disorders under maintenance care versus usual care (SDM-BD)

Acronym
SDM-BD

Study objectives
The main aim of this study is to find out whether a new digital service can be used to improve the quality of treatment for people with bipolar disorder. This study will examine two primary objectives:

The primary objectives of this study are:
1. Practicality: How the service can work alongside NHS services for patients with BD in terms of delivery and maintenance of the intervention. Measured by:
1.1. Structured audit of intervention delivery
1.2. Evaluation of service integration. This will be measured through:
1.2.1. Patient care experience. Assessed in patient interviews, using the RE-AIM framework.
1.2.2. Clinician experience. Assessed in clinician interviews, using the RE-AIM framework.
1.2.3. Coordination: Whether NHS staff feel the service improves or complicates care coordination.
Assessed in clinician interviews, using the RE-AIM framework.
1.3. Evaluation of staff training and support. This will be measured through:
1.3.1. Number of staff trained on service delivery/usage.
1.3.2. Feedback from staff on training adequacy.
1.3.3. Feedback from staff on and support for ongoing service support - Assessed in interviews.
1.4. Evaluation of the barriers and facilitators of delivering the service alongside existing workflows for BD patients in the NHS SLaM boroughs through qualitative assessment. This will be analysed in line with the RE-AIM framework

2. Acceptability: Suitability and satisfaction of the services for both patients and care teams. Measured by:
2.1. Patient engagement:
2.1.1. Patient activation measured by the Patient Health Engagement Scale
2.1.2. Number of months in which the user engages with different aspects of the service.
2.2. Service usability for patients and clinicians using the System Usability Scale
2.3. Clinician experience i.e., How the service affects clinician workload and whether they find it helpful for managing bipolar disorder patients. Assessed using the Mini-Z burnout scale alongside clinician semi-structured interviews (qualitative data).

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 06/06/2025, West of Scotland REC 5 (Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 (0)141 314 0213; WoSREC5@ggc.scot.nhs.uk), ref: 25/WS/0092

Study design
Single-centre randomized feasibility study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
This is a single-centre randomised feasibility study of 120 people with Bipolar Disorder (BD). Participants aged 18+ with a diagnosis of BD, who are not in an acute BD episode, will be recruited and, after a baseline assessment, will be randomised to one of two groups. A web-based randomisation system will be designed, using the bespoke KCTU randomisation system. One group will continue their usual treatment alongside regular use of the Fora Health platform for 6 months, while the other group will undergo their usual treatment without using the platform.

A digital health service ("Fora Health"), a UK and BD-specific service consisting of a patient smartphone app (iOS and Android) and a clinical workflow and Electronic Patient Record (EPR)-integrated and web-app-based Care Team Interface (CTI). The patient app supports patients in preparing for medical appointments by helping them to review their treatment options and express their treatment preferences using interactive patient decision aids. The app also allows treatment review, to track symptoms, side effects, medication adherence, and record Patient Reported Outcome Measures (PROMs), and can engage patients in shared decision making (SDM) before, during, and after appointments to support regular treatment review. Information gathered by the patient using the app will be shared with their relevant clinical support team in advance of any clinical encounter, and can be used to inform the conversation between the patient and their clinical team. The details of the frequency of patient interaction will depend on the frequency of the medication they take, the PROMs that are included in the app and the frequency of their appointment with the care teams. Patients randomised to receive this tool will, after randomisation, be trained in using the tool and supported in downloading it. They may then access it at their convenience over a 6-month period. Participants who discontinue will remain in the study if they are willing. Participants will also continue usual care.

Intervention Type
Behavioural

Primary outcome(s)
1. The practicality of using the service alongside NHS services for patients with BD in terms of delivery and maintenance of the intervention will be measured using data collected during a structured audit of intervention delivery (in terms of fidelity, service integration, and training) at weeks 13 and 26 and feedback from qualitative interviews following participants' week 26 visits.
2. Acceptability of how the service meets the needs of patients and care teams around SDM, measured using the Patient Health Engagement Scale (PHES) at baseline and weeks 3, 8 13, and 26, System Usability Scale at week 26, and semi-structured interviews with patients and clinicians following participants' week 26 visits.

Key secondary outcome(s))
Data collected using the four secondary outcome measures may be used in the design of future trials:
1. Stable mood state will be measured using the following patient-report scales of low and elevated affective states at baseline and weeks 3, 8, 13, and 26:
1.1. The Maudsley 3-item Visual Analogue Scale (M3VAS)
1.2. The Quick Inventory of Depressive Symptomatology (QIDS)
1.3. The Young Mania Rating Scale (YMRS)
2. Patient confidence measured using the Health Confidence tool at baseline and weeks 3, 8, 13, and 26
3. Shared decision making measured using the M-PICS and the CollaboRATE tool at baseline and week 26
4. Costs and economic outcomes measured by EQ5D-5L and Client Service Receipt Inventory at baseline and week 26

Completion date
09/05/2027

Eligibility

Key inclusion criteria
1. Aged 18 years or older at study entry (via patient report)
2. Meet DSM-5 criteria for a bipolar disorder (type I, type II, or NOS), with onset before age 50, as reported by the clinician
3. Undergoing care within South London & Maudsley NHS Trust and has an identified clinician who is willing and able to provide separate written informed consent (Please note that there are no specific criteria relating to clinicians' inclusion, besides their responsibility for the patient)
4. Ability to provide informed consent to participate
5. Access to an internet-enabled device that is supported by the Fora Health application, according to the minimum system requirements

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Currently in an acute bipolar episode (as reported by clinician)
2. Comorbid substance dependence within three months of screening, as determined by a score of 27 or higher on any domain of the Alcohol, Smoking and Substance Involvement Screening

Test v3.0 (ASSIST)
3. Comorbid organic neurological disorder (as per patient report)
4. Unable to communicate fluently in English (defined as the ability to read and understand the participant information sheet, plus the ability to communicate with the researcher throughout the screening assessment)

Date of first enrolment
03/09/2025

Date of final enrolment
28/09/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bethlem Royal Hospital
Monks Orchard Road
Beckenham
United Kingdom
BR3 3BX

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Organisation
South London and Maudsley NHS Foundation Trust

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 available upon request from Professor Allan Young (allan.young@kcl.ac.uk), subject to participants' consent. The type of anonymised data provided will depend on the nature of the request. Data will be available 26 weeks after the completion of data collection.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes