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Online integrated bipolar parenting intervention study

Submission date
31/03/2023

Recruitment status
No longer recruiting

Registration date
03/05/2023

Overall study status
Ongoing

Last Edited
18/11/2025

Condition category
Mental and Behavioural Disorders

[ ] 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
Parents with bipolar disorder (BD) find that the ups and downs of mood that they experience make parenting very challenging, particularly in providing the consistent support and guidance children need. Parents with BD want parenting support but worry they might lose access to their children if they disclose this to their clinicians. Accessible, flexible, and confidential online parenting support is a way to provide this without adding to the worries parents already have. Children of parents with BD often have emotional and behavioural problems, which can lead to severe mental health problems, including BD, as they grow up. Parents need support to help their children flourish, which may help parents themselves feel better as well, with wider benefits for society. Researchers have built an online intervention to support parents with BD, which was acceptable to parents and helped with child emotional and behavioral problems and with parenting. They now need to fully assess whether an updated version of this intervention is effective and represents value for money.
The aim of this study is to assess whether providing parents with bipolar disorder (BD) with online parenting support leads to their children having fewer behaviour problems. The researchers also want to know whether this helps parents feel less stressed and more confident about their parenting. They will also explore whether the intervention leads to parents having fewer mood or anxiety problems.

Who can participate?
Parents who experience bipolar disorder and have at least one child between the ages of 4-11 years old. Participants must be UK residents and will need access to an internet-enabled computer, tablet, or mobile phone.

What does the study involve?
The screening process involves taking part in a 15-minute initial call and then an eligibility check, which will last around 2 hours. Once confirmed as eligible, participants will be involved in the study for 48 weeks. They will be asked to fill in measures when they join the study, again after 24 weeks, and then again at the end of their involvement after 48 weeks. Participants will be randomly allocated to either receive access to IBPI and continue their treatment as usual, or to

the control group where they will have access to a web page providing information on sources of support for bipolar and parenting but no additional material beyond their treatment as usual. The surveys sent to both study groups are the same.

What are the possible benefits and risks of participating?
There may be potential benefits from using IBPI for children's emotional and behavioural problems, as well as for parenting outcomes. There is a chance participants will find no direct benefit to themselves, but it is hoped that participants will find the information in the study helpful is interesting to engage with. It is also hoped that they feel like they've made an important contribution to research aimed at improving support for parents with bipolar disorder and their families. There are no direct risks anticipated with participating in this study.

Where is the study run from?
The core trial team are based at Lancaster University (UK). This is a remote digital trial so participants will not need to travel anywhere to take part.

When is the study starting and how long is it expected to run for?
April 2022 to January 2027

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

Who is the main contact?
Lucy Cryle (Trial Manager) and Stephanie Fortier (Research Assistant), ibpi@lancaster.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
309190

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 309190, NIHR131483, CPMS 53926

Study information

Scientific Title
Clinical and cost-effectiveness of an online integrated bipolar parenting intervention: a randomized controlled trial

Acronym
IBPI

Study objectives
It is hypothesised that an integrated bipolar parenting intervention (IBPI) plus treatment as usual will improve child emotional and behavioural difficulties compared to treatment as usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/10/2022, West Midlands – Solihull Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)2071048269; solihull.rec@hra.nhs.uk), ref: 22/WM/0200

Study design
Online randomized effectiveness and cost-effectiveness trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Parents with BD with a child aged 4-10 years old in the UK will be invited to participate through UK NHS mental health trusts, mental health charities and social media. Parents who agree to take part will be offered either the online intervention or usual care. Whether the parent receives the intervention or not is decided by randomisation (like a coin toss).

Randomisation will be conducted using an online system (within the REDCap Cloud electronic data capture system) set up by the York Clinical Trials Unit. Participants will be allocated (1:1 ratio) to the two trial arms using stratified randomisation. Participants will be stratified based on

the number of previous bipolar episodes (three levels; 1-7, 8-19, or >=20), and whether or not their partner is receiving mental health care (three levels; yes, no or n/a - no partner).

The Integrated Bipolar Parenting Intervention (IBPI) is an online tool that combines parenting support with helpful strategies for managing bipolar. It has nine modules, including topics such as “anxiety”, “sleep”, “perfectionism, impulsivity, and supporting your child to learn new skills”. Sections take around 30 minutes each to complete and parents are free to access them whenever they want. IBPI can be accessed 24/7 through computers, mobile phones or tablets connected to the internet.

Parents will fill in questionnaires about their child, their parenting, their mood and anxiety when they start the study and at 24 and 48 weeks. Up to 30 parents will be interviewed after taking part in the intervention to learn their views.

Updated 17/06/2025:
The sample for the feedback interviews has reduced from n = 30 to up to n = 20 participants. A feedback survey has been added to the intervention arm (IBPI + treatment as usual) to supplement the reduction in the number of feedback interviews in the qualitative aspect of the trial.

Intervention Type
Behavioural

Primary outcome(s)
The child’s behavioural and emotional wellbeing is measured using the Strengths and Difficulties Questionnaire (SDQ) at 0, 24 and 48 weeks. The primary outcome is SDQ at 24 weeks. This will be completed by the parent about the index child.

Key secondary outcome(s))
1. Clinical: Child behavioural and emotional problems at 48 weeks, Parenting stress, confidence, and competence
2. Parental Mood: Family Functioning
3. Health Cost: Measures of parent-reported child and parent quality of life and cost at 24 and 48 weeks
4. Qualitative: Participants’ views on the intervention

1. Behavioural and emotional wellbeing of non-index children (any other eligible children aged 4-10 who parents spend 10+ hours a week with) assessed using the SDQ at 0, 24 and 48 weeks
2. Parenting stress and competency measured using the Parenting Sense of Competence Scale (PSOC), Parenting Scale (PS) and Parenting Stress Index Short Form (PSI-4-SF) at 0, 24 and 48 weeks
3. Parental mood measured with the Internal States Scale (ISS), the Centre for Epidemiologic Studies Depression Scale (CES-D), the Altman Self Rating Mania Scale (ASRM), the Generalised Anxiety Disorder Scale (GAD-7), and the National Institute of Mental Health’s Self-Rated Retrospective Life Chart Method (LCM) at 0, 24 and 48 weeks
4. Family functioning measured with the Confusion, Hubbub and Order Scale (CHAOS-9) at 0, 24 and 48 weeks
5. Cost-effectiveness determined from a societal perspective using the Child and Adolescent Service Use Schedule (CA-SUS) and the CARER-SUS in which parents will report on both their child’s and their own use of health, social, and educational services, as well as time off work for parents in employment. These will be completed by parents at 0, 24 and 48 weeks.

6. Parent-reported child and parent quality of life (CHU-9D; EQ-5D-3L) and cost (CA-SUS; CARER-SUS). Using these measures, the researchers will determine quality-adjusted life years (QALYS) for parents (EURO-QOL Research Group, 2018) and children (Stevens, 2012). These will be completed by parents at 0, 24 and 48 weeks.
7. Demographic information about the parent and their index child collected via self-report questionnaires at 0 weeks only

Feedback interviews
Following the completion of the Internal Pilot, a subset of participants (n = 30) will be selected and invited to participate in a feedback interview. This will only apply to participants from the IBPI + TAU arm, not from the TAU arm. Participants will be selected with maximum variance sampling on stratification factors and levels of intervention use for feedback interviews. The topic guide for these interviews will include questions surrounding participants' perceptions of what has changed following IBPI, the factors which influenced their level of engagement, and their recommendations for improvement.

Completion date
31/01/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 17/06/2025:
1. Bipolar diagnosis of parent confirmed by structured clinical interview
2. Have a child aged 4-11 years with ≥10 hours of face-to-face contact weekly
3. Internet access
4. Ability to provide informed consent
5. Resident in the UK

Previous inclusion criteria:
1. Bipolar diagnosis of parent confirmed by structured clinical interview
2. Have a child aged 4-10 years with ≥10 hours of face-to-face contact weekly
3. Internet access
4. Ability to provide informed consent
5. Resident in the UK

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 years

Upper age limit
11 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Primary parent diagnosis of alcohol/other substance misuse
2. Parents already receiving a parenting intervention and/or intensive psychotherapy
3. Index child in receipt of current psychological therapy
4. Child subject to child protection proceedings

Date of first enrolment
07/03/2023

Date of final enrolment
30/11/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Lancaster
University House
Lancaster
England
LA1 4YW

Sponsor information

Organisation
Lancaster University

ROR
https://ror.org/04f2nsd36

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 the current study will be stored in a publicly available repository (Lancaster University Research Directory (Pure Portal: https://portal.lancaster.ac.uk/ask/pure/)). Metadata will be publicly available, but anonymised participant survey data will be access-controlled and available on request with approval from the Chief Investigator (CI), subject to a data sharing agreement. Consent by participants has been obtained for their data to be used for secondary analysis. Consent has also been obtained for data to be stored for up to 10 years in the repository, with optional consent for data to be analysed during this 10-year period. Qualitative data will not be made available as pseudo-anonymised data might still contain details that may identify individuals. Anonymised quotes, however, will be access-controlled and made available on request with approval from the CI.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		26/08/2025	27/08/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 9.1	12/01/2023	24/04/2023	No	Yes
Participant information sheet	version 10.0	27/03/2025	17/06/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes