Clinical and cost effectiveness of an online integrated bipolar parenting intervention: A randomised controlled trial

IBPI Trial Protocol Version 3.4

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2. List of Abbreviations

ASRM: Altman Self-Rating Mania Scale

BD: Bipolar Disorder

CARER-SUS: Carer/Parent Service Use Schedule

CA-SUS: Child and Adolescent Service Use Schedule

CES-D: The Center for Epidemiological Studies-Depression

CHAOS: Confusion, Hubbub and Order Scale

CHU-9D: Child Health Utility Questionnaire

DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition

EQ-5D-3L: Quality of Life Questionnaire

GAD-7: Generalized Anxiety Disorder Assessment

IBPI: Integrated Bipolar Parenting Intervention

IDMC: Independent Data Monitoring Committee

ISS: Internal States Scale

LCM: Life Chart Measure

PPI: Public and Patient Involvement

PS: Parenting Scale

PSI-4-SF: Parent Stress Index 4 Short Form

PSOC: Parenting Sense of Competency

REDCap: Research Electronic Data Capture

SCID-5: Structured Clinical Interview for DSM-5

SDQ: Strengths and Difficulties Questionnaire

SURG: Service user reference group

TAU: Treatment as Usual

TMG: Trial Management Group

TSC: Trial Steering Committee

YTU: York Trials Unit

3. Trial Summary

	Clinical and cost effectiveness of an online integrated bipolar parenting intervention: A randomised controlled trial
Trial Design	Online randomised controlled effectiveness and cost effectiveness trial
Trial Participants	Parents with bipolar disorder in the UK Inclusion Criteria: • Bipolar Disorder (BD) diagnosis of parent, confirmed by structured clinical interview • Have a child aged 4-10 years with ≥10 hours of face-to-face contact weekly. This is defined as the 'index child'. Where more than one child in the family meets these criteria, the parent is asked to select one child as the focus for child behaviour and parenting assessment • Internet access • Ability to provide informed consent • Resident in UK Exclusion Criteria: • Primary parent diagnosis of alcohol/other substance misuse • Parents already receiving a parenting intervention and/or intensive psychotherapy • Index child in receipt of current psychological therapy • Child identified by social services/multi-agency partners due to current or ongoing child protection concerns • 3 cancelled or missed eligibility check calls without providing at least 1 days' notice
Planned number of participants	342
Study duration	48 weeks per participant
Primary Outcome	Child behavioural and emotional problems at 24 weeks for the index child measured using the Strengths and Difficulties Questionnaire
Secondary Outcomes	**Clinical** Child behavioural and emotional problems at 48 weeks for index child and at 24 and 48 weeks for any non-index children Parenting stress, confidence, and competence Parental Mood Family Functioning **Health Cost** Measures of parent-reported child and parent quality of life and cost at 24 and 48 weeks

	Qualitative Participants' views on the intervention
Intervention	This trial will compare the clinical and cost effectiveness of 1) Integrated Bipolar Parenting Intervention + Treatment as usual (TAU) 2) TAU

4. Trial Flow Chart

Potential participant hears about the study and self-refers by filling in their contact details on the LU website

Potential participant is contacted by their GP/local Trust regarding their possible eligibility. Potential participant is directed to the LU study website and fills in their contact details

Research team contact potential participant to arrange an informal screening interview, which verifies that they:

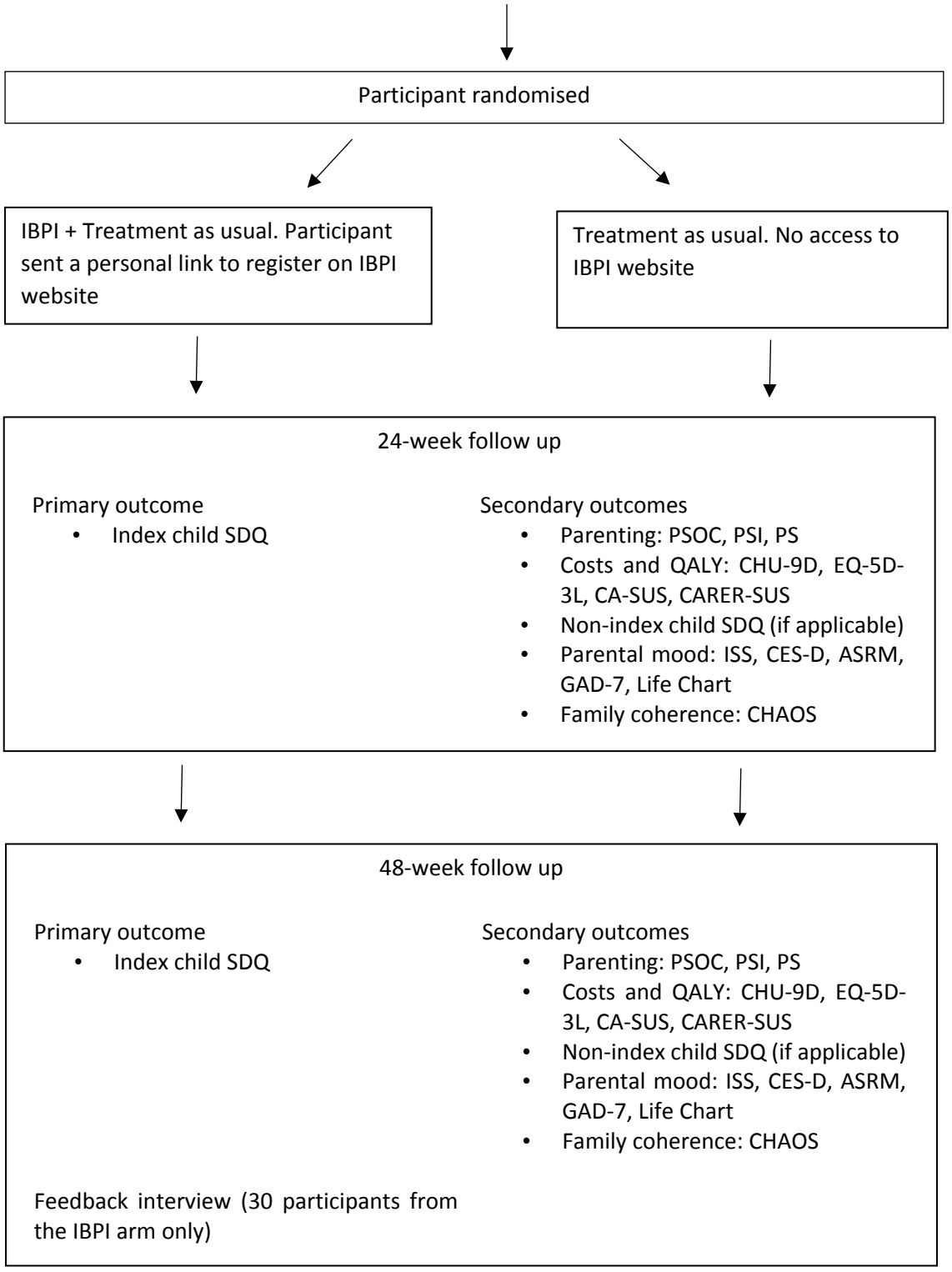
- Have a child aged 4-10 years with ≥10 hours of face-to-face contact weekly
- Have internet access
- Have the ability to provide informed consent
- Feel they experience BD
- Are a resident in UK

If eligible, the research team will email the potential participant a link to the online consent form, which will be hosted either on YTU's REDCap or on a Lancaster University Microsoft Form

After consenting, participants are contacted again by researcher to have an eligibility check to confirm BD diagnosis. If eligibility criteria are met, participant is then linked back to REDCap to complete baseline measures

Baseline

- Sociodemographic questionnaire
- Family questionnaire
- Index child SDQ
- Parenting: PSOC, PSI, PS
- Costs and QALY: CHU-9D, EQ-5D-3L, CA-SUS, CARER-SUS
- Non-index child SDQ (if applicable)
- Parental mood: CES-D, ASRM, LCM, ISS, GAD-7
- Family coherence: CHAOS


Participant randomised
IBPI + Treatment as usual. Participant sent a personal link to register on IBPI website
Treatment as usual. No access to IBPI website
24-week follow up
Primary outcome
Index child SDQ
Secondary outcomes
Parenting: PSOC, PSI, PS
Costs and QALY: CHU-9D, EQ-5D-3L, CA-SUS, CARER-SUS
Non-index child SDQ (if applicable)
Parental mood: ISS, CES-D, ASRM, GAD-7, Life Chart
Family coherence: CHAOS
48-week follow up
Primary outcome
Index child SDQ
Secondary outcomes
Parenting: PSOC, PSI, PS
Costs and QALY: CHU-9D, EQ-5D-3L, CA-SUS, CARER-SUS
Non-index child SDQ (if applicable)
Parental mood: ISS, CES-D, ASRM, GAD-7, Life Chart
Family coherence: CHAOS
Feedback interview (30 participants from the IBPI arm only)

5. Summary of Research

5.1 Background and Rationale

Parents with bipolar disorder (BD) and their children need better access to effective support. Approximately 800,000 UK children live with a parent with BD (ONS, 2013; ONS, 2017; McManus et al., 2016). These children face additional challenges with unstable parental involvement impacting on their behavioural and emotional wellbeing (Rasic et al., 2014). Anxiety disorders, depression and BD are two to six times more likely in children of parents with BD, compared to children of parents without mental health problems. Parents with BD can fluctuate between being highly competent and engaged, to struggling with routine parenting tasks due to their current mood (Fristad, 2010; Calam et al., 2012 and Venkataram, 2011). As a result, parents report high parenting stress and low parenting competence/confidence, causing them significant distress (Tjoflåt & Ramvi, 2013; Dolman et al., 2013).

Despite these issues, there are no specific interventions to support parenting in BD. Offering accessible, evidence–based parenting programmes specifically for parents with BD may reduce immediate distress in children, help parents, and potentially mitigate the risk of future severe mental health issues in adolescence and adulthood (Jones et al., 2017; Duffy et al., 2016). Parenting programmes reduce child behaviour problems, including ADHD, conduct disorder and antisocial behaviour (NICE, 2013) and symptoms of emotional problems (i.e. anxiety and depression) (Cartwright-Hatton et al., 2005). They typically foster adaptive parenting through information and support based on social learning and cognitive behavioural principles (Sanders, 2012).

However, we do not know whether generic parenting interventions work for parents with severe mental health issues and there is good reason to think they need interventions tailored to their specific concerns (Bee et al., 2014; Schrank et al., 2015). Parents with BD typically do not access generic parenting programmes or acknowledge parenting challenges to mental health services due to stigma and fear of losing child custody (Dolman et al., 2016). Despite this, parents with BD want parenting self-management interventions (Calam et al., 2012). For parents with BD, a parenting programme will need to support them with living with BD as well as providing parenting support linked to the specific challenges their children experience (Jones et al., 2017; Duffy et al., 2016).

There is evidence that online parenting support is accessible and has the potential to be effective, confidential, and flexible. However, there is no definitively evaluated online intervention specifically designed for parents with BD. It is therefore crucial that, based on our promising feasibility trial (Jones et al., 2017), the Integrated Bipolar Parenting Intervention [IBPI] is definitively tested in terms of clinical and cost effectiveness. We hypothesise that IBPI will improve the child's clinical and functional outcomes.

5.1.1 *IBPI Feasibility Trial*

Our feasibility study showed that delivering online parenting support to parents with BD is feasible, was positively received, safe, and showed positive signals for improving child behavioural and emotional outcomes as well as parenting confidence, competence, and stress (Jones et al., 2017), although not powered to test clinical effectiveness. No investigation of clinical economic outcomes was undertaken. 97 parents were randomised to receive either IBPI or treatment as usual. The intervention was accessible only via PC and combined bespoke text, video, and self-reflection information on BD with access to an established online parenting intervention (Triple P) developed in Australia (Turner & Sanders, 2011). Participants had a significant BD history of 7 years duration on average, with 93% reporting more than 6 episodes of depression and 73% more than 6 episodes of mania. Forty five percent of participants were unemployed and/or in receipt of disability support, indicating significant socioeconomic disadvantage.

5.1.2 *Proposed changes from Feasibility Study*

The following changes have been informed by the feasibility study, our qualitative work from the feasibility study, feedback from our service user reference group during that study, PPI consultation with parents with bipolar disorder in preparation for this application, and expert guidance from clinical members of the applicant team. These changes will retain the simplicity and ease of navigation of the IBPI intervention with relatively brief modules combining accessible text information, video, interactive exercises, and opportunities for self-reflection. These elements were valued by participants who often reported having little time between their parenting roles, their bipolar challenges and other day-to-day responsibilities.

1. **Full Integration of bipolar and parenting elements of the intervention.** Participants valued the intervention but felt that the original Triple P elements were not relevant as they were not specifically tailored to parents in the UK with BD. Some also reported that accessing the Triple P modules felt frustrating as they were not fully integrated with the BD content. We will therefore extend the bespoke modules with additional tailored parenting information informed by well-established parenting interventions (Leijten et al., 2019)

2. **Future proof the intervention making it readily accessible on both mobile and PC/laptops.** IBPI was accessible by PC/laptop but recent ONS data highlights that 89% of internet users access the internet 'on the go' through mobile phones (ONS, 2019). The updated version of IBPI will therefore be equally accessible on Apple and Android mobile platforms and through PC/laptop.

3. **Increase diversity of the participant group.** In our feasibility study, we were successful in recruiting to target and our participants were similar in profile to participants in face-to-face trials in terms of patterns of repeated episodes and high levels of unemployment/disability. However, the ethnic diversity of the group was low with over 90% of participants identifying as white British. To improve this, our PPI plan includes targeting people from ethnic minority backgrounds to ensure that recruitment and intervention materials are inclusive. We also plan our recruitment strategy to include NHS and third sector providers that specifically support people from ethnic minority backgrounds. Our approach will be guided by NIHR's equality diversity and inclusion policy and informed by NIHR's Toolkit for: Increasing participation of Black, Asian and Minority Ethnic (BAME) groups in Health and Social Care Research (Faroqi et al., 2018).

5.2 Aims and Objectives

The aim of this study is to determine the clinical and cost effectiveness of the Integrated Bipolar Parenting Intervention (IBPI) plus treatment as usual [IBPI] compared to treatment as usual (TAU) [Control] on child behavioural and emotional difficulties. In fulfilling this aim, we will pursue the following objectives:

1. Determine the clinical effectiveness of IBPI on the primary outcome

i) Child behavioural and emotional problems at 24 weeks. Measured using the Strengths and Difficulties Questionnaire (SDQ, [Goodman, 2001])

2. Determine the clinical effectiveness of IBPI on the secondary outcomes

i) Child behavioural and emotional problems at 48 weeks, measured using the SDQ.

ii) Parenting competence, confidence, and stress at 24 and 48 weeks. Measured using the Parenting Scale (PS [Arnold et al., 1993]), the Parenting Sense of Competency Scale (PSOCS,

[Johnston & Mash, 1989]), and the Parenting Stress Index Short Form (PSI-4-SF, [Abidin, 1990]).

iii) Parental mood (self-rated mania and depression) at 24 and 48 weeks. Measured using the Internal States Scale (ISS, [Bauer et al., 2000]), the Centre for Epidemiologic Studies Depression Scale (CES-D, [Radloff, 1991]), the Altman Self Rating Mania Scale (ASRM, [Altman et al., 1997], the Generalized Anxiety Disorder Scale (GAD-7, [Spitzer et al., 2006]), and the Life Chart Method – Retrospective (LCM-r, adapted from the NIMH-LIFE [Leverich & Post, 1998]).

iv) Family coherence at 24 and 48 weeks. Measured using the Confusion, Hubbub, and Order Scale (CHAOS, [Matheny Jr et al., 1995]).

3. **Determine the cost effectiveness of IBPI**

i) A comparison of costs and quality adjusted life years (QALY) for IBPI vs TAU will be conducted at 24 and 48 weeks. Measures of child behavioural and emotional problems (SDQ), QALY gains for child (Child Health Utility 9D, CHU-9D, [Stevens, 2012]), QALY for parent (3-level EQ-5D, EQ-5D-3L, [Euroqol Research Group, 2018]), parent service use (Carer/Parent Service Use Schedule, CARER CA-SUS, []) and child service use (Child and Adolescent Service Use Schedule, CA-SUS, []) will be used for this comparison.

4. **Obtain the views of IBPI recipients on their experiences of IBPI**

i) A qualitative interview (referred to as a feedback interview, as the term qualitative is not well understood by participants) will be conducted with selected participants from the IBPI arm of the trial following completion of the internal pilot. The topic guide for these interviews will include questions surrounding participants' perception of what has changed following IBPI, the factors which influenced their level of engagement, and their recommendations for improvement.

6. Methods

6.1 Trial Design

The trial is an online-randomised controlled effectiveness and cost effectiveness trial. Analysis of the SDQ (24 weeks primary outcome) and other secondary outcomes will be by via constrained longitudinal data analysis (cLDA) models, adjusting for factors used in the randomisation. This has been informed by MRC (http://www.mrc.ac.uk/documents/pdf/rcts-for-complex-interventions-to-improve-health/ and www.mrc.ac.uk/documents/pdf/good-clinical-practice-in-clinical-trials/), SPIRIT (http://www.spirit-statement.org/), and CONSORT (http://www.equator-network.org/reporting).

6.2 Study Setting: UK

This study will take place online in the UK, with Lancashire and South Cumbria NHS Foundation Trust (LSCFT) as the lead NHS trust. The study is UK-specific because parenting practises may differ between countries and cultures, and the IBPI will be specifically for parents in the UK with guidance most relevant for this group. If successful, the intervention may be adapted in the future for testing and use in other countries and cultures.

6.3 Recruitment and Retention

6.3.1 *Recruitment process*

The trial will recruit participants in two ways. Firstly, based on clinician referrals from NHS primary and secondary care services. As such, the trial will seek to work in partnership throughout the recruitment process with all mental health NHS Trusts and as many GP practices from across the UK as possible. Clinician based recruitment will be facilitated with support from the Clinical Research Network (CRN), who will streamline the establishment of these primary and secondary care services as Participant Identification Centres (PICs). To do so, the Primary Care Research Network (PCRN) and the CRN will work together to send expressions of interest out to all relevant GP practices and NHS Trusts in the UK. Services that are interested in acting as PICs will respond to the enquiry and will be put in contact with the research team to begin the recruitment process.

Recruitment here will look slightly different in primary and secondary care. Primary care PICs will be asked to conduct a database search and eligibility check in order to identify patients suitable for IBPI. They will then be asked to approach these patients to invite them to the study by SMS using a provided SMS patient invitation template. GPs may choose to invite patients to the study by post or email using a provided patient invitation letter instead, at their discretion.

Secondary care PICs will be asked to identify teams to support IBPI. These teams may then be asked to review their caseloads to identify potential participants. Clinical teams may then approach identified service users who are not subscribed to NHS opt-out to invite them to the study using the patient invitation letter. Clinician approach in secondary care may take place in person as part of routine clinical appointment, or by post or email during non-clinic times.

Alternatively, secondary care recruitment may also be supported by local Trust staff with legitimate access to patient data. The CI may delegate the duty of identifying and approaching potential participants to local staff, such as the Trust employed RA. To do so, local staff will request reports be ran to identify the NHS numbers of service users at the Trust who meet the inclusion criteria for IBPI. They will then run these NHS numbers through the NHS opt-out service, and will approach patients who have not opted-out to inform them of the study using the patient invitation letter. Before the invitation letter is sent, patients' clinical teams will be given the opportunity to provide any other reason why the service user should not be contacted for research (i.e. recent bereavement). Local Trust staff access to patient records is legitimate, complies with data protection legislation and NHS confidentiality code, and is supported by the NHS constitution. This method of participant identification and approach is consistent with our method in primary care which has been very successful through the internal pilot, and has also been approved and implemented with success at LSCFT on other NIHR trials, such as CO-PACT and ADEPP.

The patient invitation letter will state the study's aims, describe what participation will entail, and explain what IBPI is. Importantly, these letters will also provide the potential participants with instructions for how to register their interest through the study's website, for which a web address will also be included. Potential participants will use this link to register their interest in the study themselves.

Finally, PICs will also be responsible for promoting and encouraging recruitment to the trial both on site and online. To do so, the Trusts and GPs will be asked to display physical (i.e. flyers and brochures) and digital (i.e. animated adverts or videos on waiting room televisions) recruitment media on site. They will also be expected to distribute recruitment adverts online, including using

the Trusts' social media accounts with established followings on various platforms to do so on a national scale.

Secondly, potential participants may also self-refer themselves to the study. Study advertisements will be delivered through a variety of means, including:

• Physical and digital adverts in primary and secondary care services' (GP, hospital, pharmacy, etc.) waiting areas

• NHS service-user support groups and carer support groups, e.g. newsletters, social media accounts and face-to-face meetings. The Trial and the Clinical Studies Officers will present the study at peer support and carer support groups

• National mental health organisations and charities websites, newsletters, groups, and conferences

• Social media

• Lancaster University press office

• Community outreach through events and advertising in schools, community centres, religious buildings, children's centres, etc.

As with our previous studies, targeted advertising on social media and Google be used, as well as online promotion through the charity Bipolar UK. In line with previous studies run by Lancaster University, we will also have blog-style posts written by the trial team and those with lived experience to support the study and encourage participation. These posts will be shared through networks such as Bipolar UK's eNewsletter. All of the adverts here and above will guide potential participants to the study information website, where they will be able to learn more about the trial and register their interest in participation.

6.3.2 *Recruitment from study website*

The study website (www.lancaster.ac.uk/spectrum/ibpi) is currently available for study promotion and information sharing. Following ethics approval, this website will also allow potential participants to register their interest in participation. Potential participants will register their interest via the embedded Microsoft Forms link. On the registration form, they will be asked to enter their contact details (phone number, email address, and postal address). This information will be stored to allow a member of the research team to contact them directly to answer any questions they may have about the study, to arrange their initial screening interview, and for later contact about follow up assessments. This personal data will only be stored for 12 months following completion of the study, at which point it will be deleted. Based on previous studies, we expect it will take an average of 7 days for participants to reach baseline assessments after initially registering their interest, and that recruitment will come from approximately 50% online and social media activities and 50% through NHS sources (Jones et al., 2017; Lobban et al., 2020).

6.3.3 *Retention Process*

Participant attrition is one of the biggest challenges faced by online trials, with limited research into the most effective ways to maximise participant retention online (Frampton et al., 2020). Our retention strategy has been informed by a previous study run by Lancaster University, REACT (Lobban et al., 2020), as well as our feasibility study and a recent meta-analysis (Thongseiratch et al., 2020). To maximise retention in the current study we will:

- Include an explanation in the Participant Information Sheet to explain why data completion at follow-up is important
- Only randomise participants once they have completed the measures at baseline
- Send participants a schedule of email and telephone reminders to prompt engagement with the intervention and with each assessment point, based on successful strategies in REACT
- Pay participants who complete all of the questionnaires £10 after each assessment point. Paying participants has been shown to improve retention [59, 60] and evidence from the REACT trial showed that offering more money did not lead to further retention improvements
- Send participants a Thank You certificate, to aid with parent and child compliance
- Allow participants who may be unable to complete all follow-up measures to only complete some of them, with an emphasis on the primary outcome measure (SDQ)
- Allow participants to complete assessments at times and locations of their choosing by using online self-report measures. This should increase retention as participants can pick convenient times and locations for them
- We have inflated our sample size to allow for 25% drop-out rate

6.3.4 *Internal Pilot*

Our feasibility study demonstrated that IBPI is acceptable, safe, and potentially helpful to children and parents. However, an internal pilot will be included for the current study to confirm that it is possible to recruit to scale considering its sample size is over three times that of the feasibility study (see Table 1). We plan to recruit 342 participants over a 24-month period. An internal pilot will be conducted over the first 8 months of the recruitment period, which is equivalent to 35% of the total window for recruitment. The internal pilot has a recruitment target of n=75 (22% of total study target, beginning n=1 per month in month 1, to n=11 per month in month 5 raising to n=16 in month 7 and n=17 per month in month 8). This target takes into account the staggered set-up of patient identification centres (PIC's), time required to fully optimise online recruitment approaches. Recruitment figures will be regularly reviewed at trial management meetings and the Trial Steering Committee (TSC) to ensure that any missed targets are noticed and rectified quickly. LSCFT are the host trust, and the remaining 59 mental health trusts will be approached to be recruited as PICs. We aim to have all NHS mental health trusts actively promoting the study. Online recruitment should be fully optimised by the end of the pilot phase (month 15), thus we anticipate an increased recruitment rate from this point onwards at a rate of 16-17 participants per month. This is based on a rate of >50 participants per month in the post internal pilot phase of the REACT trial, which used similar methods.

Table 1 shows the STOP /REVIEW/ GO criteria for the internal pilot.

	Red - STOP	Amber - REVIEW	Green - GO
Total number of participants recruited after completion of the internal pilot	0-44 participants (<60% of recruitment target)	45-74 participants (60-99% of recruitment target)	>=75 participants (>=100% of recruitment target)
Outcome	Stop – unless demonstratable	Discuss with TMG and TSC strategies to improve	Proceed

	mitigating circumstances	recruitment, including additional site and proceed with funder permission	

6.4 Participants

6.4.1 *Sample Size*

A total of 342 participants will be recruited for the trial, with 171 allocated to IBPI and treatment as usual, and 171 allocated to treatment as usual. To detect a target effect of 2 points on the SDQ total score (assuming SD=6.46 and baseline-outcome SDQ correlation=0.65), a total sample size of 256 participants is required for 90% power. Conservatively inflating this to allow for 25% attrition (19.6% had missing data on 24- week SDQ in pilot trial), the total sample size for randomisation will be 342. In practice, power will be increased slightly due to the use of constrained longitudinal data analysis.

6.4.2 *Inclusion Criteria:*

- **BD diagnosis of parent, confirmed by structured clinical interview** (First et al., 2015). This intervention is specifically tailored for individuals living with clinically established BD so it is crucial this is confirmed
- **Have a child aged 4-10 years with ≥10 hours of face-to-face contact weekly.** The focus of the feasibility and this definitive trial is to support parents with BD of young children they are in regular contact with. This age group offers the opportunity for early intervention in a high-risk group likely to develop additional significant mental health issues in adolescence without appropriate support. We recognise families will often have several children, so the parent will identify an index child for the duration of the trial
- **Internet access.** This is required to ensure that people can access the online assessments and intervention. A limited number of internet dongles can be offered to participants without reliable internet connection
- **Ability to provide informed consent**
- **Resident in the UK.** The intervention has been designed for people in a UK context, including UK information on sources of information and support

6.4.3 *Exclusion Criteria:*

- **Parents with primary diagnosis of alcohol/other substance misuse.** Parents with primary substance use issues are likely to require different support to those for whose BD is the primary issue so the planned intervention would be less relevant
- **Parents already receiving a parenting intervention and/or intensive psychotherapy.** The receipt of different forms of psychological support at the same time could be confusing for the parent and would make it difficult to determine the impact of IBPI
- **Index child in receipt of current psychological therapy.** There is a risk that messages from therapy could be different from what parent is doing based on IBPI. It would also risk masking effects of the current intervention. Non-index children, however, can currently be receiving psychological therapy
- **Child(ren) identified by social services/multi-agency partners due to current or ongoing child protection concerns.** Such protection concerns could impact parent access and therefore make the focus of the intervention less relevant

- **3 cancelled or missed eligibility check calls without providing at least 1 days' notice.** Requests to cancel or rearrange an eligibility check less than 24 hours prior, or unattended calls, severely restrict the number of participants that can be welcomed into the trial. Based on PPI feedback, we will allow participants 3 chances to attend a call and after this time they will not be offered another, meaning they are by default excluded.

6.4.4 *Participant Withdrawal*

Participants will be free to withdraw from the trial at any time without providing a reason, although we will ask if they'd like to give a reason so that we can learn from their experiences and consider this in future studies. Participants can withdraw from the IBPI arm (i.e. using the intervention website) and/or withdraw from providing data for the follow-up questionnaires. For the former, their account and login details will be deleted and they will no longer have access to the IBPI site. For the latter, they will not be sent the follow-up measures and reminders about these. Alternatively, participants will be able to withdraw from follow-up in which they do not complete measures at a particular assessment point (partial withdrawal) or do not complete all assessments (we will encourage participants to complete the primary outcome measure, the SDQ, if they do not want to complete all assessments). In an effort to encourage engagement with the follow-up assessments, participants will receive the following series of reminders to complete the follow-ups (until follow-up is completed):

- Up to three automated e-mail reminders at 5-day intervals
- A manual text message from the trial team 3 days after the final automated e-mail, with the participant's log-in details and instructions on how to complete the follow-up
- A telephone call from the trial team 3 days after the text message, asking the participant to complete the questionnaires online, but offering to complete the primary questionnaire over the telephone. If the participant does not answer, a second attempt will be made; an answer-machine message will be left if this too is unsuccessful
- A postal pack containing a letter, the primary questionnaire and a reply-paid envelope, and an automated text message triggered by the trial manager through the trial dashboard. The message will contain prespecified text and a link to complete the primary questionnaire on their mobile phone

Although participants will be free to withdraw at any time, under the university's lawful basis for processing data for research, they will not be able to withdraw, change, or access any questionnaire data they have provided prior to this point. This will be made clear in the Participant Information Sheet.

6.4.5 *Participant Timeline*

1. **Expression of interest**

Potential participants will be identified through clinicians or will be self-identified following exposure to study advertisement (see 6.3.1). Potential participants will then be directed to the study website, which will have been set up prior to recruitment. The website will describe the aims of the study, what IBPI is, how the intervention works, and so on. The website will also inform potential participants of the study's inclusion criteria, and will invite those who qualify to register their interest in participation by completing a Microsoft Forms questionnaire. Microsoft Forms will be used to collect potential participants' phone numbers, email addresses, and postal addresses so that a member of the research team can contact them to arrange the initial one-to-one screening interviews. In line with GDPR guidance, the form will also require participants to consent to

Lancaster University storing their personal information for a period of up to 1 year following study completion before it can be submitted to the research team for use.

2. Screening

As a national trial, the screening and consenting process for this study has been designed to be entirely remote to minimize burden on participants. Potential participants will first be invited to complete an initial remote screening interview with a member of the research team, either by telephone or by video call (their choice). Here, the researcher will explain the study to the potential participant, confirm that they are likely to meet inclusion criteria, and answer any further questions they might have. In an effort to increase the diversity of the trial's demographics, the research team will also host drop-in screening events. The drop-in screenings will be held either in person or remotely, and will allow potential participants to join at their convenience during an advertised period of time. These events will be advertised within local communities and online. At the drop-in screenings, potential participants will have the opportunity to learn more about the study, ask any questions, and determine their eligibility for participation. This flexible community approach to recruitment and screening aims to increase sample diversity by making the study more accessible for underrepresented groups such as ethnic minorities. This is based on the experience of the ROSHNI-D trial (Masood et al., 2015) and their success engaging with this population.

If a potential participant is indeed eligible and wants to continue after the initial screening interview, they will be directed to an online Participant Information Sheet and online consent form. These documents will be hosted on York Trials Unit (YTU)'s REDCap and/or Lancaster University's Microsoft Forms. Here, the participants will be asked to provide consent to participation in an eligibility check, which has been developed from the research version of the SCID (structured clinical interview for DSM-5). Participants will also provide consent to the trial as a whole (bar the feedback interview), and to having their anonymised research data stored for 10 years following completion of the trial. This consent is separate from, and in addition to, the consent to contact form that they will have provided during their expression of interest. Participants will be allowed at least 24 hours to provide informed consent, but can take longer if they wish. Upon receipt of this information, a researcher will then contact the participant by email to collect their GP/Care Coordinators contact details and to arrange a remote meeting (telephone or video call) for their eligibility check. GP/Care Coordinator contact details will be collected using a Lancaster University Microsoft Form and will be stored using Lancaster University Microsoft Teams. These contact details will be used to inform clinicians of their patients' involvement in the study, and to let them know if a patient experiences a high-risk adverse event during their time as a participant. The purpose of the eligibility check is to confirm potential participants' diagnosis of bipolar disorder. As a thank you, the potential participant will receive £40 for their time completing the eligibility check (regardless of its outcome), as per the NIHR's guidance on paying participants. Eligibility checks will be recorded for safety reasons, including for clinical consult, but will not be transcribed or analysed as part of this research. Recordings of the eligibility check will be securely destroyed once the potential participant's eligibility has been decided. If significant risk is identified through participant responses during their screening or eligibility check, or through their interaction with the research team, then the TM also reserves the right to contact the emergency services and/or the participant's GP/Care Coordinator as appropriate. In situations where safeguarding issues are identified, such as disclosure of risk of harm to self or others, confidentiality will need to be broken and the research team will inform the police or social services of an emergency, and appropriate measures will be taken to ensure the welfare of any children involved.

3. Baseline Measures

After their eligibility check, the research team will send each participant links to the baseline assessment measures for them to complete (online, using YTU's REDCap Cloud platform). The assessment will be comprised of all the self-report measures (see 6.5), as well as sociodemographic and family background questionnaires. If participants experience distress or feel they need technical support while completing the questionnaires, they will be able to call a member of the research team or request by email that a researcher rings them back within 1 working day for further assistance. It should also be noted here that if at baseline (or at either follow-up) participants score beyond the clinical thresholds (see 9.3.1) on any of the mood questionnaires, then they will be sent supportive emails and/or texts with resources which signpost them to third-sector or NHS support.

4. Randomisation

After baseline, the participants will be randomised to either receiving IBPI plus TAU or TAU alone. Randomisation will be conducted using an online system (within the REDCap Cloud electronic data capture system) set up by YTU. Participants will be allocated (1:1 ratio) to the two trial arms using stratified randomisation. Participants will be stratified based on number of previous bipolar episodes (3 levels; 1-7, 8-19, or >=20), and whether or not their partner is receiving mental health care (3 levels; yes, no, or n/a – no partner).

5. IBPI Intervention

The participants who are allocated to the IBPI arm will be emailed a link to the IBPI website with their login details. This email will also stress the importance of keeping its contents, along with the contents of the website, confidential so as to avoid any risk of contamination. In the interest of confidentiality, participants will be asked to enter their date of birth and gender when registering for the website. This information will automatically be crossed checked with the information provided at baseline so as to ensure only those allocated to the IBPI arm are accessing it. Importantly, IBPI will be accessible to the allocated participants 24 hours a day, 7 days a week, as website or an app from either a desktop, laptop, tablet, or mobile phone. For more information on IBPI (see 6.7).

6. Follow-Up Assessments

At 24 and 48 weeks, reminders to complete the follow-up questionnaires will appear on the IBPI site. Participants in both arms of the study will also be sent email and text reminders prompting them to complete the follow-up measures. All the measures will be self-reported by participants online using YTU's REDCap system. Moreover, since assessments are being completed remotely, participants will have the convenience of engaging with the questionnaires at a time and place that suits them best. Participants will also receive £10 after each assessment point as thanks for completing the measures. Should the participants experience distress at any time while completing the follow-up assessments, they can email the team to request a call back within 1 working day, or ring the research team directly for more immediate support. Instructions on how to access this support along with research team contact information will be available within the PIS and CF. The PIS will also contain clinical resources for further support, as the research team is not an emergency clinical service. Finally, once the Internal Pilot recruitment targets have been met, some participants from the IBPI arm will also begin to be invited to participate in a feedback interview (see 6.5.5).

7. Dissemination and Access to Site

After the study period is over, participants will be invited to an online conference where the results of the trial will be shared. Participants will also be sent a plain-English summary of the research findings (written by our Service User Reference Group) and an accessible animation showing the purpose and outcomes of the research.

Participants from the control arm of the trial will be able to access IBPI after the trial is over. The preparation for maintaining, managing and updating IBPI after the trial is over has already begun, depending on a positive outcome of the trial. For more information on the intervention after the study, see *Intervention – IBPI After the Trial.*

6.5 Measures

6.5.1 *Primary Outcome Measure*

To assess the child's behavioural and emotional wellbeing, the Strengths and Difficulties Questionnaire (SDQ) will be completed by the parent about the index child. If the participant only has one eligible child, then this will be their index child. If the participant has multiple eligible children, they will select one child as their index child to base their primary SDQ responses on throughout the duration of the trial. Participants may also complete subsequent SDQs relating to their other eligible children, referred to as "non-index children".

The SDQ was selected as the primary outcome to evaluate children's behavioural and emotional problems. It has an established factor structure with strong internal consistency and test-retest reliability. Moreover, in line with the aims of the study, high SDQ scores are consistently found to be strongly predictive of psychiatric disorders (Goodman et al., 2001). The SDQ is widely used and sensitive to change in parent and teacher mediated intervention studies, and in intervention studies to improve quality of life in children of parents with serious mental illness (including Bee et al., 2014; Ford et al., 2019; Sanders et al., 2012; Patterson et al., 2002, and Scott et al., 2001). This was confirmed in our proof of principle and feasibility studies [Jones et al., 2014; 2017).

6.5.2 Secondary Outcome Measures

The SDQ will also be completed by parents about any other eligible children they have (i.e. aged 4-10 who they spend 10+ hours a week with), to assess non-index children's behavioural and emotional wellbeing, as well as to inform sensitivity analyses (see 7.2).

To assess parenting stress and competency, parents will be asked to complete the Parenting Sense of Competence Scale (PSOC), Parenting Scale (PS) and Parenting Stress Index Short Form (PSI-4-SF). These three parenting measures capture the multifaceted nature of parenting across confidence, competence, and stress. The PS, PSOC and the PSI-4-SF all have strong psychometric properties and were sensitive to change in the feasibility study (Jones et al., 2017; Arnold et al., 1993; Jonston & Mash, 1989; Abidin, 1990; Prinzie et al., 2007).

Parental mood will be 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). The LCM has been jointly adapted by the research team and clinical experts to provide an efficient and accessible means of identifying whether the participant has experienced episodes of mania, hypomania or depression during the follow up period. All of these measures of parental mood have evidence for validity, reliability and sensitivity to change [Bauer et al., 2000; Radloff, 1991; Altman et al., 1997; Spitzer et al., 2006; Jones et al., 2018).

Finally, family functioning will be measured with the Confusion, Hubbub and Order Scale (CHAOS-9). CHAOS-9 is well documented by the literature as a reliable, sensitive measure whom is correlated

with a wide range of physical, emotional, and academic outcomes in children (Matheny Jr et al., 1995; Marsh et al., 2020). It is important to note that the selection of these outcome measures was informed by Ritzer et al.'s recent Core Outcome Set for use in community-based bipolar trials qualitative study (2020). Specifically, this NIHR funded study (RP-PG-0611-20004) identified domains of measurement critical to community-based bipolar trials (Retzer et al., 2020), of which the present study's measures cover the core domains of connectedness, bipolar symptoms, wellbeing, and quality of life. Likewise, prior research on validity, reliability, and sensitivity of measures, including findings from our feasibility study, was equally key in this trial's selection of outcome measures.

6.5.3 *Sociodemographic Measures*

Demographic information about the parent and their index child will be collected via self-report questionnaires at baseline. The inclusion of this self-report strategy has been informed by its successful implementation during our feasibility trial. We will collect:

- Parent's age, gender, and ethnicity
- Child's age and gender
- Number of children per family
- Whether the participant's partner is in receipt of current mental health treatment
- Number of previous bipolar episodes

6.5.4 *Cost-effectiveness*

Cost will be determined from a societal perspective using the 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.

Measures of parent reported child and parent quality of life (CHU-9D; EQ-5D-3L) and cost (CA-SUS; CARER-SUS) will be completed at baseline, 24 weeks, and 48 weeks. Using these measures, we will determine quality adjusted life years (QALYS) for parents (EURO-QOL Research Group, 2018) and children (Stevens, 2012).

6.5.5 *Feedback interviews*

Following completion of the Internal Pilot, a subset of participants (n=30) will begin to be selected and invited to participate in a feedback interview. This will only apply to participants from the IBPI arm, and only to those who consented to be contacted about the feedback interview when completing the main consent form. Participants will be selected with maximum variance sampling on minimisation factors and levels of intervention use for feedback interviews. Participants will be asked to review a separate PIS and to provide further informed consent ahead of taking part in this interview. This is separate from and in addition to the PIS and informed consent they will have already provided as part of the rest of the trial. The purpose of this interview will be to gain a better understand of participant experiences with the IBPI website, such as what worked well, what still needs to be improved, and why. The feedback interview will also explore participants' appraisal of their time spent on the trial, what they feel like they learned from the intervention, and patterns of website use. Importantly, this interview will also ask participants to share their perceptions of what has changed for them and their child as a result of their completion of the intervention, and will look to identify any barriers/facilitators to engagement. In line with the NIHR's guidance on paying participants, participants will receive £40 as a thank you following their completion of their feedback interview. The topic guide for these interviews will be co-developed with our Service User Reference Group (SURG). Interviews will take place over the telephone or live video conference according to participant preference. Interviews will be recorded and transcribed for analysis. Recordings will be securely destroyed following completion of pseudonymised transcription.

6.6 Data Collection

All measures will be hosted and completed on YTU's REDCap Cloud. Demographic assessments will be collected at baseline. Assessment of all the outcome measures will be conducted at baseline, then again at both 24- and 48-weeks post randomisation. See *Table 2* for a full schedule of assessments during the trial period. Following completion of the internal pilot, subset of participants will be invited to participate in a feedback interview (see 6.5.5). This post-pilot assessment point was chosen order to ensure the satisfaction of the trial's recruitment targets, whilst also optimising accurate participant recall of their experiences.

Table 2 shows the trial's Schedule of Assessments

	Pre-Randomisation	**Randomisation**	**Post-Randomisation**	
	Registration	0-weeks	24 weeks	48 weeks
Initial Screening	□			
Informed consent	□			
Eligibility check to confirm BD diagnosis	□			
Randomisation		□		
Intervention				
Integrated Bipolar Parenting Intervention		◄———	———	———►
Clinical				
Sociodemographic Questionnaire		□		
Family questionnaire		□		
SDQ		□	□	□
PS, PSOC, PSI		□	□	□
CES-D, ASRM, LCM, ISS, GAD-7		□	□	□
CHAOS		□	□	□
Health Economic				
CHU-9D, EQ-5D-3L, CA-SUS, CARER-SUS		□	□	□
Feedback interviews*		◄———	———	———►

**Following completion of the internal pilot*

6.7 Intervention

The integrated bipolar parenting intervention (IBPI) is an online tool designed to enhance self-management and parenting skills for people with BD. The IBPI intervention is underpinned by:

i) cognitive social learning theory indicating the importance of improving interaction patterns between parents and children, with key roles for modelling and self-efficacy (Bandura, 1977; Patterson, 1982)

ii) cognitive behavioural theory highlighting the importance of providing evidence-based information to improve coping styles and increase stability of behaviour and mood in bipolar disorder, and knowledge about the nature and impact of bipolar disorder (Lam et al., 2010)

6.7.1 *Initial Development of IBPI*

The IBPI website was initially developed in collaboration with parents with BD (Jones et al., 2015). In the feasibility study, participants had access to the IBPI intervention, an eight-module self-management intervention, as well as a separate parenting program; Triple P. Feedback from the feasibility trial will inform all updates made to the IBPI site before the launch. Key amends to the site will include more closely integrating the parenting and BD aspects of the intervention and general improvements to the look and feel. This will be done with the continuous feedback and ideas from our PPI group as well as academics and clinicians.

6.7.2 *The IBPI Intervention website*

The IBPI website will have 9 information modules. Each module will have information and advice for parents on each topic, as well as interactive and multimedia features including video clips, interactive exercises, and self-evaluation exercises. The site will have a normalising, self-regulating focus to avoid stigmatising or blaming participants. Based on our feasibility trial, each module is expected to take around 30 minutes for participants to complete and they are expected to access one module per week. The IBPI will be accessible to participants in the IBPI arm of the trial 24 hours a day, 7 days a week, as a website or an app from desktops, laptops, mobile phones, and tablets.

6.7.3 *IBPI Redevelopment*

The IBPI website will be refreshed during the first six months of the study, before recruitment begins. This will be based on the feedback from the feasibility study, input from people with lived experience of parenting with bipolar, and input from academics and clinicians. The refresh will also update the interface of the IBPI site according to modern standards so that it can be made available as both an app and a website.

The current titles for each section are as follows, however these may change before recruitment begins, in response to iterative feedback from service users, academics, and clinicians.

- Parenting and bipolar disorder overview
- Benefits and challenges of bipolar in relation to parenting
- Understanding mood variation to help manage your child's behaviour consistently
- Monitoring your mood
- Perfectionism, impulsivity and supporting your child to learn new skills
- Managing relationships and change
- Dealing with anxiety
- Managing Sleep
- The importance of making time for yourself and planning ahead

6.7.4 *IBPI after the Trial*

The preparation for maintaining, managing, and updating online resources after the trial has already begun. The applicant team have an established successful relationship with our partners LSCFT and Bipolar UK who will implement it post-trial. We are working with ORCHA and NHSx to ensure that resource is implementation ready on completion including DTAC compliance. Jeremy Clark, Mental Health Policy Manager at NHSx has agreed to contribute to oversight of this process through bimonthly meetings with the PI and research team. Resources will be created in open-source software to ensure ease of maintenance and updating. Based upon a positive outcome of the trial, LSCFT have agreed to support the site after the completion of the research, in collaboration with Bipolar UK. LSCFT have a successful track record of implementing digital initiatives as part of their role as an NHS global digital exemplar trust (e.g. leading national take of Attend Anywhere remote visit software). Bipolar UK, as the national third sector organisation for people with bipolar and their

relatives, has an established digital presence including forums and chat bots that this resource would complement. The online resources platform will be part of LSCFT's wider online hosting infrastructure. Content refreshment will be included in a Trust annual review of online resources, in collaboration with the LSCFT Communications Dept. Updates will be devised by LSCFT clinical staff in partnership with Bipolar UK and in consultation with the Spectrum Centre for Mental Health Research at Lancaster University.

6.7.5 *Treatment as Usual*

We will not make any direct changes to current treatment as part of the trial. Participants will be informed that taking part in the trial will not affect any support or services that they, or their child, receive. We will assess current treatment using the CA-SUS and the CARER-SUS, both of which assess for use of health, social, and educational services.

6.8 Procedure

Once either self- or clinician-identified, potential participants will be directed to the study's information webpage, wherein they will find more information about the study. Here, potential participants will be able to view the study's inclusion criteria, and will be invited to register their interest if they are eligible and would like to participate. To do so, potential participants will be asked to submit their contact information (email address, phone number, and postal address) via Microsoft Forms using the link provided on the website. In doing so, participants will also be asked to consent to having their personal information stored by Lancaster University so that a member of the research team can contact them to arrange their screening and, if eligible, eligibility check. If the screening interview confirms the potential participants meet the inclusion criteria, they will then be directed to the study's online PIS and consent forms. At this stage, participants will have at least 24 hours to provide consent to taking part in the eligibility check, as well as in the trial as whole (not including the feedback interview). Upon receipt of informed consent, each participant will then be contacted again by a member of the research team to request contact details for their GP or Care Coordinator and to schedule his or her eligibility check. GP/Care Coordinator contact details will be collected using a Lancaster University Microsoft Form and will be stored on a Lancaster University Microsoft Teams channel that only the core trial team members will have access to. GP/Care Coordinator contact details will be used to inform participant's clinicians of their patient's involvement in the study. This information will also be used to contact GPs/Care Coordinators if their patient is identified as being of significant risk to themselves or others at any time during the study. The GP/Care Coordinator contact details request form will be sent to participants in the same email that is used to schedule their eligibility check; however, this form must be returned completed before the eligibility check can go ahead. If the eligibility check confirms a bipolar diagnosis, participants will then be emailed links to the baseline self-report measures, to be completed online using YTU's REDCap Cloud platform. It is important to note here that risk management procedures will be in place throughout the duration of the trial. Specifically, if at any time a participant is identified as being at low-risk through their questionnaire responses (see 9.4.1), then they will receive a supportive email from the trial team with resources signposting them to third-sector or NHS support. Similarly, if at any time a participant is identified as being at high risk through their interview responses or interactions with the trial team (see 9.4.2), then a member of the research team will contact the participant's clinical team and/or the emergency services as appropriate.

Once the baseline assessments have been completed, participants will be emailed their mood diaries. The mood diaries will contain 12 blank LCM-r questionnaires (exactly the same as included at baseline and follow-ups). Participants will be asked to record their moods at the end of each month

by completing one LCM-r in their diary. The purpose of the mood diary is strictly to serve as a memory aide to help participants to complete the LCM-r at 24 and 48 weeks on REDCap. At no point in time will these diaries be viewed or requested by the research team. Participants are simply being encouraged to create these memory aides about their symptoms in order to optimise the accuracy of their recall during assessment. As such, while participants will be asked to engage with their mood diaries monthly, it will also be explained to participants that at a bare minimum they are to be completed once every 3 months, meaning participants are expected to have done at least two new mood diary entries ahead of each follow-up point.

Participants will also be stratified and randomised at this time using an online system (within the REDCap Cloud electronic data capture [EDC] system) set up by YTU, so as to ensure allocation is concealed until participant consent and registration are confirmed. Once a participant has been randomised, their GP or Care Coordinator will then be sent a letter or email from the research team to inform them of the study and to say that their patient is taking part in the trial.

Participants allocated to the TAU arm will be emailed their login details and a link to a separate page of the study information website. This will be a password-protected webpage which houses links to external parenting, bipolar, and distress resources to help support these participants throughout the trial as they will not have access to the intervention until completion of the study. Those allocated to the intervention arm will receive an individualised link to register with the IBPI site via email. They will record date of birth and gender at registration to ensure this matches information provided at baseline assessment. They will then be free to access the IBPI site when they want to, 24 hours a day, 7 days a week. This means that participants can access the intervention as frequently as they like and at times most convenient for them. The analysis will follow intention to treat, meaning that even if participants do not access the site or access it very little, they will still be included in the between-group analysis.

At 24 weeks and at 48 weeks from randomisation, participants in both trial arms will be prompted to complete the various self-report measures. They'll be prompted to complete the assessments (and reminded about uncompleted assessments) using a schedule of email, mobile and postal contact, (and directly on the IBPI site) which successfully enhanced data completeness in previous studies by our team. Participants in the intervention arm will also be prompted about the assessments directly on the IBPI site. The measures will be completed online, using YTU's REDCap Cloud. Participants will also receive a £10 payment as a thank you for completing the questionnaires at each of the two assessment points. This has been shown to improve retention (Brueton et al., 2014; David & Ware, 2014) and there was no evidence from the REACT trial that offering more money led to further retention improvements.

Following completion of the internal pilot, a subgroup of participants (n=30) from the IBPI arm will be recruited for feedback interviews sampled across minimisation variables and levels of use of IBPI to understand their subjective experience of the intervention. This will include topics such as what has changed for them and their child as a result of using the intervention, their patterns of use and what influenced these, and suggestions for improvement. The interview topic guide will be co-developed with our SURG. Interviews will take place over telephone or live video conference according to participant preference. Interviews will be recorded and transcribed for analysis.

We will obtain consent to share de-identified data for secondary analyses and to follow up the sample after this trial, subject to further separate grant funding. The aim would be to understand how improving child behaviour problems impacts future risk of more severe mental health issues through adolescence and longer-term benefits for parents with BD.

7. Analysis

Analysis will be 'as randomised' (intention-to-treat), where participants are analysed according to their allocation, regardless of whether they received that treatment or not. A confidence level of 95% and corresponding 5% significance level will be used in the analysis of the primary and secondary outcomes. Full details of the analysis will be included in a Statistical Analysis Plan (SAP) which will be developed by the Trial Statistician prior to analysis, and approved by the Trial Management Group (TMG) and Trial Steering Committee (TSC).

7.1 Primary Outcome

The primary outcome is the SDQ score for the index child at 24 weeks. The 24 week assessment point was chosen for the primary outcome as this allows sufficient time for participants to learn, adopt and implement behaviour changes to improve child wellbeing consistent with underpinning theory (Bandura, 1977; Patterson, 1982; Lam et al., 2010). This is informed by feasibility data indicating: i) over 95% of participants completed using IBPI by 3-4 months, leaving 2-3 months for this learning to be translated to child outcomes; ii) SDQ slopes diverge baseline to 24 weeks between arms then plateau to 48 weeks (indicating maintenance in the second 24 weeks period). This primary outcome mirrors that of previous parenting intervention trials, aiding comparison of effects (Scott et al., 2010; Patterson et al., 2002).

To make use of all available observations from all time points in the study, the estimate for the 24-week between-groups difference will be derived from a constrained longitudinal data analysis (cLDA) model (Coffman, 2016). The model will be a linear mixed effects model, featuring SDQ score for the index child as outcome, intervention group, time-point, the stratification as fixed effects, and participant identifier as a random effect. Intervention group-by-time-point interaction effects will be included for each of the 24-week and 48-week time-points, thereby making no assumptions about the shape of the SDQ score trajectory over time. The model will be constrained so that the expected baseline SDQ scores are equal in the two groups (Coffman, 2016). Parameter estimation will use maximum likelihood, with an unstructured covariance matrix. The between-groups difference in SDQ score at 24 weeks (primary outcome) and 48 weeks (secondary outcome) will be extracted (i.e. the respective group-by-time-point interaction effect estimates) and reported from this model

7.2 Secondary Outcomes

Secondary outcomes will also be analysed using cLDA models, with adjustment for the stratification factors. Sensitivity analyses will include a cLDA model for SDQ scores (baseline, 24 weeks, 48 weeks) for all eligible children, with fixed effects as for the primary analysis model, but two random effects: the participant (parent) identifier and the child (within-parent) identifier.

7.3 Qualitative Data Analysis

Analysis will follow the framework approach of Ritchie and Spencer (2002). The initial framework will be based on the need to understand what people felt changed as a result of IBPI as well as patterns of use and what influenced these. This initial framework will evolve through familiarisation and indexing to produce final themes.

7.4 Measurement of costs and outcomes

The main analyses will be based on all randomised participants (ITT population) at 24 weeks (primary) and 48 weeks. The 24-week endpoint was chosen to be consistent with the end point for the primary outcome measure. The 48-week economic analysis will assess jointly the resource and clinical implications following treatment.

The direct costs will be estimated from resource use data combined with published national unit costs. These include the Department of Health Reference costs (Department of Health, 2013), the Unit costs of Health and Social Care produced by the Personal Social Services Research Unit, University of Kent (Curtis, 2013), and the British National Formulary. Each item of healthcare service use will be assigned a cost by multiplying the quantity of service used with the average unit cost for that item. The cost-effectiveness of the treatment groups will be compared incremental costs effectiveness ratios (ICERs), defined as the difference between the treatments arms in mean costs divided by the difference in mean effects. If the IBPI group has lower costs and better outcome than TAU it will be interpreted as the dominant treatment. If one of the treatment groups is more effective and more costly than its comparator then trade-offs will need to be considered. To reveal the nature of these trade-offs a cost-effectiveness acceptability curve (CEAC) will be plotted for each cost outcome combination. We will use non-parametric bootstrapping for the costs and effectiveness data to generate the joint distribution of incremental mean costs and incremental effects. This will allow us to show the likelihood of one treatment arm being seen as cost-effective relative to another treatment arm given different (implicit monetary) values placed on incremental outcome improvements.

8. Ethical Considerations

8.1 Ethical Approval

Before commencing recruitment, we will gain ethical approval from HRA (Health Research Authority) and the Sponsor (Lancaster University). Every member of the research team that will be in contact with participants will have a research passport. Research passports will require researchers to obtain or provide evidence of a DBS check and an occupational health check, as well as of training in Good Clinical Practice (GCP), information security, and assessing risk. All staff will be up to date with training in Good Clinical Practise (GCP), information security training, and assessing risk. The Trial Management Group and the Trial Steering Committee will ensure all activity is carried out according to protocol. The YTU will oversee all data collection, storage, and management and ensure that this is anonymous and secure and consistent with the Data Protection Act (2018). Access to data and data management systems will be restricted to YTU staff and the trial team so as to preserve confidentiality and blindness. The trial will be registered and given an ISRCTN number. Once finalised, a protocol paper and statistical analysis protocol will be published.

8.2 Informed Consent

We will seek valid informed consent from participants online. Following the British Psychological Society's guidance (2021), we will provide participants with detailed online participant information sheets that will include clear information about data rights, withdrawal rights, and the risks and benefits of taking part. We will collect informed consent from participants using of a series of online consent forms, all of which will contain explicit consent statements that each require a response from the participant. Informed consent will be collected a maximum of three times throughout the trial. Participants will consent once to having their personal details stored in line with GDPR guidance, once to the eligibility check and trial as a whole, and (if selected) once to the feedback interview. Participants will also consent to both their own and their child/children's data being collected and analysed by the research team, in order to confirm that the parents understand that while their child/children will not be participating in the study, information about them and their behaviour will be collected through parents' self-reported responses. Consent forms for each of these stages of the trial will be stored either by Lancaster University or by York Trials Unit.

8.3 Potential Risks and Benefits to Participants

8.3.1 *Potential Risks and Burdens*

There are three areas of potential risks and burdens that we have identified. These are 1) participant distress, 2) burden/inconvenience of IBPI site, 3) data privacy and confidentiality.

1) Participant Distress

Participants may be at risk of distress during the eligibility check (based on the SCID diagnostic interview) and the feedback interviews. The eligibility check covers past mood experiences and challenges, which may cause distress. However, participants may also welcome the opportunity to talk about their experiences in a structured format. The feedback interviews will be focussed on the participant's experience of the IBPI site rather than distressing experiences specifically, however, sensitive and distressing topics may still arise. If a participant experiences distress in either the eligibility check or feedback interview, the interviewer will encourage the participant to take a break and remind the participant that they are free to withdraw and end the interview at any time, without needing to give a reason. The interviewer will be an experienced researcher who will have received additional sensitivity training from the PPI lead, as well as training for the eligibility check from the CI and other grant holders who are experienced clinicians. In the interest of wellbeing, if a participant does become distressed during either of the interviews, and the interviewer identifies the situation as a low-risk adverse event, then the participant will be given the option of pausing or ending the interview. They will also be sent a supportive email following the conclusion of their interview which signposts them to relevant NHS and third-sector support. If the interviewer believes a participant's responses or behaviours during either of the interviews (eligibility check or feedback interview) indicates they are at significant immediate risk of harm to themselves or others, this will be reported as a high-risk adverse event. Similarly, if any other contact between the participant and the research team indicates immediate risk to life of the participant or their child, then a high-risk adverse event will again be identified. In response to any high-risk adverse event, a member of the trial team will break confidentiality and contact the participant's GP, Care Coordinator, and/or the emergency services as appropriate.

The questionnaires at each assessment point may also cause distress as participants reflect on their mental health. Participants will have the option for a support call with a research assistant within 1 working day of each assessment point. Furthermore, they will be reminded that they are free to withdraw from the study at any point. Participants can either withdraw completely or partially - where they complete measures some but not all. Moreover, participants' scores on the mood and parenting questionnaires at each assessment points may suggest they're at low risk. To address this, participants will be sent supportive emails with information about NHS and third sector support if their (or their child's) measures of mental health (ASRM, CES-D, GAD-7) are reported beyond clinical thresholds (see 9.3). Likewise, the Participant Information Sheet will contain a section of "Resources for Dealing with Distress", including links to relevant third sector contact numbers as well as contacts within the research team, which participants may find useful to refer to throughout their participation in the study.

2) Burden/Inconvenience of the intervention and follow-up

Participants may find the need to visit the IBPI website burdensome if it takes up too much time, or if they are required to access it at times which conflict with their schedule. Furthermore, completing the follow-up measures could present further time management burdens that are perceived as inconvenient by the participants. As such, in an attempt to make IBPI as convenient as possible, the website will be available 24 hours a day, 7 days a week. This means that participants can choose to

access the website as frequently as they like, at times that are always convenient for them. At no point will participants be told they have to visit the website, nor will they ever be required to visit the website at any specific times dictated by the research team. Similarly, the follow-up measures will also all be completed online, so participants can choose where and when they want to complete them. REDCap has a 'save progress' function to allow participants to complete measures over a series of visits rather than all at once, to make completion easier to fit into their lives. The trial participation process as a whole has been designed with participants in mind, and as a result, their experience should be as comfortable and convenient as is possible. Participants will also be paid £10 after each follow-up assessment point, as well as £40 following their eligibility check and feedback (for those selected) interviews as a thank you for their time.

3) Data Privacy and Confidentiality

Participants may be concerned about how their data will be stored and accessed. The research team will work in line with GDPR requirements as well as Lancaster University's data management policy (https://www.lancaster.ac.uk/library/research-data-management/research-data-management-policy/) and guidance (https://www.lancaster.ac.uk/library/research-data-management/). The Participation Information Sheet will include information on GDPR laws, participants' rights, and how their data will be processed, stored and accessed. The Participant Information Sheet will also include "Resources for finding out more about data protection and storage", with a link to Lancaster University's data management policy, a link to the HRA's guidance on patient information in research (https://www.hra.nhs.uk/information-about-patients/) as well as contacts within the research team, should they have any questions.

8.3.2 *Potential Benefits*

As indicated by the feasibility trial, there are potential benefits from using IBPI for children's emotional and behavioural problems and for parenting outcomes. In our experience from similar previous studies, participants have valued the experience of learning more about parenting and bipolar, as well as contributing to improving interventions for other individuals with these experiences.

Participants will be paid £10 at each assessment point as a thank you for completing the questionnaires. They will also be paid £40 for the eligibility check and for the feedback interview respectively. This payment is in line with NIHR's payment guidance for research - https://www.nihr.ac.uk/documents/payment-guidance-for-researchers-and-professionals/27392. Where participants are unable to accept BACS payments, the trial team will offer vouchers of equal value.

9. Trial Monitoring

9.1 Project Management

The primary clinical trial manager and admin support will be based at the Spectrum Centre and supervised by SJ and FL. The RA will be based in LSCFT and in Spectrum and will receive day-to-day supervision from the TM overseen by SJ. The intervention site will be maintained by Lancaster University's ISS (Information Systems and Services) IT Partnering and Innovation (ITPI) team, who will work closely with the Spectrum centre's research team. Operational supervision meetings will take place regularly. There will be a monthly TMG of all applicants to review progress in relation to the project milestones and solve any issues arising in reaching these. YTU will provide recruitment and retention data for this meeting so that this can be actively monitored. The SURG will meet regularly

and feed into the trial management meeting through the PPI lead. SURG members will have additional funded sessions to input into the optimising of the IBPI intervention and to plan and execute the PPI dissemination and implementation strategy. There will also be an independent data monitoring committee (IDMC) and trial steering committee (TSC) that will meet one to two times per year throughout the trial to review the trial's progress and safety.

9.2 Data Management

9.2.1 Physical Data Management

Data stored on portable devices will be encrypted. Any identifiable data, such as recordings of the participants' voices from the interviews, will be deleted as quickly as possible (when it has been transferred from the recorder to a secure password protected PC) and in the meantime the recorder will be stored securely. Eligibility check recordings will be securely deleted from password protected computers once the trial team comes to a final decision regarding the potential participants eligibility. Similarly, feedback interview recordings will also be securely deleted from password protected computers. This will come following the completion of each interview's pseudonymized transcript. Likewise, participant's GP/Care Coordinator contact details will only be stored for as long as is necessary for the purpose of our processing, and so will be securely destroyed following participants' completion or withdrawal from study activities. Computers and laptops which store personal data will be password protected. They will not be left unlocked unattended. They will also have up-to-date antivirus protection installed. All study documents will be stored digitally using a Lancaster University Microsoft Teams account, and only members of the research team will have access to the IBPI Team.

9.2.2 Maintaining Confidentiality

All personal data will be stored in accordance with the General Data Protection Regulation and Data Protection Act 2018. All data will be collected and stored securely using Lancaster University's approved IT systems and services in accordance with Lancaster University's Data Protection Policy (https://www.lancaster.ac.uk/media/lancaster-university/content-assets/documents/strategic-planning--governance/publication-scheme/5-our-policies-and-procedures/DataProtectionPolicyv1.2FINAL.pdf), Information Security Policy (https://www.lancaster.ac.uk/media/lancaster-university/content-assets/documents/strategic-planning--governance/publication-scheme/5-our-policies-and-procedures/Information-Security-Policy.pdf) and data security guidance (https://answers.lancaster.ac.uk/display/ISS/Security+of+data+and+information), which is aligned with the good industry practice and controls as defined in the ISO27001 family of standards.

Participants will be assured that their data will remain confidential to the research team and stored securely, apart from in situations where imminent risk is identified. If a clinical or safeguarding issue where an immediate and serious risk of harm to self or others is identified by the research team, the researcher will be required to break confidentiality and inform the appropriate services (police or social services) as an emergency. In these incidences, the participant's GP/Care Coordinator will also be contacted and appropriate measures will always be taken to ensure the safety and welfare of any children involved. Participants will consent to this safety protocol ahead of participation in the trial. Personal data will be stored for up to 1 year after the study ends as it may be accessed to inform participants of the findings of this research and/or to assess the research quality. Participant's GP/Care Coordinator contact details will be stored only for the duration of a participant's time on the trial. Following their completion of study activities, this data will be securely destroyed. In line with University policy, anonymised study data may be stored for up to 10 years on a password protected database managed by Lancaster University.

It is expected that communication with participants regarding their participation in the study will primarily take place by email. All IBPI and research team emails will originate from password-protected email accounts from either Lancaster University or Lancashire & South Cumbria NHS Foundation Trust, which are only accessible from password-protected computers/laptops.

The consent to contact form, as well as the consent forms for the full trial (including eligibility check) and feedback interviews, and the Participant Information Sheets will be sent to participants using either Microsoft Forms or REDCap. Lancaster University Microsoft Forms may be used to collect any of these consent forms. All consent forms collected using Microsoft Forms will then be stored on a Lancaster University Microsoft Teams channel that is only accessible to the core trial team members, and will require a Lancaster University IT account for access, which is protected by two factor authentication. Lancaster University Microsoft Forms and Microsoft Teams will also be used in the same way to collect and store participant's GP/Care Coordinator contact details. Consent for the full trial (including the eligibility check) may also be stored securely by YTU via REDCap. All questionnaire data provided by participants will also be stored in REDCap. Access to the study interface will be restricted to named authorised individuals granted user rights by a REDCap administrator at YTU. Consent forms held by Lancaster University may be shared with YTU to be stored securely on REDCap if necessary.

All documents containing personal details (such as participant email addresses and phone numbers) will be stored on a dedicated, password-protected University Office 365 Microsoft Teams account, accessible only by members of the research team through a Lancaster University login page. Lancaster University Microsoft Teams is rated for the storage of all types of data, including personal and special category data, consistent with GDPR requirements. Access to the Teams channel containing personal information will be given only to members of the team who require access for research purposes.

YTU will also have access to participant's personal data so they can randomise participants. YTU is experienced in conducting online trials and in ensuring confidentiality of personal data, in accordance with GDPR requirements.

With regards to participants' use of the intervention itself, anonymised engagement with the IBPI website will be monitored by the trial team. Engagement will be monitored in order to learn more about participants' use of the website, such as how often it is accessed, which pages are visited most and how these patterns of use relate to outcomes for participants. This will be done by linking patterns of use with anonymised participant outcome data. As such, at no time will personally identifiable information be accessed for this purpose. Participants will consent to this monitoring of their use of the IBPI website ahead of their participation in the trial.

9.2.3 *Data Management after the Study has ended*

As per Lancaster University's Research Data Management policy (www.lancaster.ac.uk/library/research-data-management/research-data-management-policy), research data will be retained for a period of 10 years within the institutional data repository, PURE, unless ethical considerations, participant confidentiality, FOI requirements or external agencies e.g. NHS, specifically require otherwise. Upon completion of the study, data will be moved to this repository and removed from any other storage location (e.g. Lancaster University Microsoft Teams or university computers). Participants will not be identifiable from the data stored. Recordings and transcripts of interviews will only be available on request and approval from the CI, to protect the anonymity of the participant. Access to the dataset will also only be available for research purposes, on request and approval from the CI. Data will be destroyed after 10 years, following Lancaster

University's data disposal guidance (https://answers.lancaster.ac.uk/display/ISS/Security+of+data+and+information).

9.3 Risk Assessment

9.3.1 *via the study questionnaires*

Participants' scores on the mood and parenting questionnaires at each assessment points may suggest they are at risk of distress. If a participant's scores go beyond clinical thresholds outlined below on the follow-up questionnaires, an email will be sent with resources and to signpost the participant to third-sector or NHS support.

Clinical thresholds for mood questionnaires, triggering supportive emails:

CES-D: 24 (Radloff, 1991)

ASRM: 6 (Altman et al., 1997)

GAD-7: 15 (Spitzer et al., 2006)

9.3.2 *via interaction with the participant*

The PIS will have contact details (email and phone) for the CI and the TM, who participants can contact with their concerns, complaints, or if they have been harmed throughout the study. The TM will also have email and/or phone contact with non-responders to encourage follow-up completion. Should a low-risk issue arise during this contact the TM will send an email/phone call to signpost the participant to contacts and resources for support. Should a high-risk issue arise, the TM will inform the participant's GP, Care Coordinator, and/or the emergency services as appropriate.

Risk may also be identified during interviews with the research team. Researchers will be trained to conduct the eligibility check and to identify risk; if significant risk, or immediate risk to life or child is identified, then the emergency services (police or social services) and the participant's GP or Care Coordinator will be contacted by the trial manager.

9.4 Identifying and Reporting Adverse Events

9.4.1 *Adverse Events (AEs)*

Low risk adverse event (AE): no indication of immediate or serious threat of severe harm or risk to life but either:

- clear evidence of high levels of distress, or
- concerns for risk of harm or abuse towards participants or others (safeguarding risks)

The most likely adverse event to occur in this study is participant experience of distress. Completing questionnaires about mood or completing interviews may cause distress.

9.4.2 *Serious Adverse Events (SAEs)*

High risk serious adverse event (SAE): clear evidence of immediate and serious risk to life or child welfare

9.4.3 *Identifying Adverse Events*

Low and high risk (S)AEs will be identified in the following ways:

a) System identifies “red flag” item in response to follow-up questionnaire items (trial team notified via email)

OR

b) Risk is identified by the research assistant if participants report harm or complaints during the eligibility check or feedback interview

OR

c) Risk is identified by the TM when contacting non-responders for follow-up (NB. This is with both arms and needs to follow strategies to ensure blinding is not broken)

OR

d) Risk is identified by the TM or Chief Investigator if participants get in contact over email or phone with complaints or reports of harm

9.4.4 *Reporting Adverse Events*

1. **Low risk events** should be documented on the relevant database within 1 working day
2. **High risk events** should be documented on the relevant database AND reported to an unblinded trial team member within 1 working day
   - The unblinded trial team member will collect relevant info about the event and forward this to TSC chair
   - The TSC chair will decide whether the high-risk event is related or unrelated to the study
   - IF RELATED then CI and TM will be unblinded
   - The TM will report the high-risk related event to TSC Chair, the Sponsor and the NHS REC within 15 days of the event
3. All AEs and SAEs will be reported at the IDMC and TSC meetings

Harms will be reported descriptively, including the number and nature of (S)AEs and number of participants with at least one (S)AE.

9.5 Data Monitoring

In line with NIHR research governance guidance (https://www.nihr.ac.uk/documents/research-governance-guidelines/12154), the Trial Steering Committee (TSC) will meet at least annually to review trial progress and conduct and consider substantial protocol amendments. Professor Sam Cartwright-Hatton, a leading expert in interventions for parents with mental health issues to improve child outcomes, has agreed to be the independent chair, subject to HTA approval. The TSC will also include an independent statistician, a PPI member, the Trial CI, and HTA and sponsor representatives as observers. This will be attended by the Trial Statistician and Health Economist.

The Independent Data Monitoring Committee (IDMC) will also meet at least annually to monitor trial data with a primary focus on ethical and safety issues. This will comprise a chair (Professor Matthias Schwannauer) and contain experts in BD, parenting, and trial statistician.

9.6 Quality Assurance

- The study will be conducted in accordance with procedures identified in the protocol.
- The trial will be overseen independently by the IDMC and the TSC.
- The IDMC will evaluate data for compliance with protocol, focussing on ethical issues and participant safety
- The TSC will evaluate the process for consent, recruitment, and randomisation for compliance with the protocol.

9.7 Record Retention

Data will be uploaded directly to a database securely managed by YTU (with access for the TM to contact non-responders for follow-up) and the relevant files will be transferred to Lancaster University as sponsor once the study has finished. Personal data will be stored for 12 months following study completion. Anonymised research data will be stored on Microsoft Teams as hosted on Lancaster University's secure, password-protected Office 365 account for up to 10 years after the study ends.

10. Indemnity

This study will be sponsored by Lancaster University. Lancaster University legal liability cover will apply to harm to participants arising from the management of the research; the design of the research; and the conduct of the research. Lancaster University will not pay compensation in the event of harm to participants where no legal liability arises.

11. Trial Committees

11.1 Trial Management Group (TMG)

The TMG (all co-applicants, Trial Manager, CTU supervising statistician) will meet monthly the duration of the trial, over video calls. Recruitment and retention data will be reported at the TMG meetings, so the progress of the trial can be monitored. This group will ensure that all the milestones are being met on time and problem solve any issues arising at any of the sites.

11.2 Trial Steering Committee (TSC)

The TSC will oversee the progress of the trial, provide guidance as required, ensure that it is being carried out according to protocol and will make decisions regarding the continuation of the trial. They will liaise directly with the trial sponsors. In line with NIHR research governance guidance (https://www.nihr.ac.uk/documents/research-governance-guidelines/12154), the TSC will meet at least annually to review trial progress and conduct and consider substantial protocol amendments. Professor Sam Cartwright-Hatton, a leading expert in interventions for parents with mental health issues to improve child outcomes, has agreed to be the independent chair, subject to HTA approval. The TSC will also include an independent statistician, a PPI member, the Trial CI, and HTA and sponsor representatives as observers. This will be attended by the Trial Statistician and Health Economist.

11.3 Independent Data Monitoring Committee (IDMC)

The Independent Data Monitoring Committee (IDMC) will meet pre-start and at least annually to monitor trial data with a primary focus on safety of participants and ethical issues. This group will be independent and will comprise a chair, experts in BD, parenting, and trial statistics.

11.4 Service User Reference Group (SURG)

The SURG will consist of 6 people with lived experience of bipolar and parenting. The SURG will meet monthly and feed into the trial management meeting through the PPI lead. The SURG's meetings will input into optimising the IBPI site, recruitment planning, sensitivity training of research assistants, development of participant information sheets, consideration of implementation issues and addressing other operational issues that may arise during the study. Regular SURG meetings will be supplemented by a dissemination-planning meeting towards the latter half of Phase 2 to co-produce a final dissemination strategy, including engaging materials for patients and members of the public. Chris Lodge (PPI lead) will convene SURG meetings and attend team management and grant holder meetings to ensure the priorities of bipolar parents are a key element of all relevant study decisions.

11.5 Trial Operational group

Operational supervision meetings will take place weekly. These will include the primary clinical trial manager, research assistants, chief investigator, and IT specialist who will all be based at the Spectrum Centre. These meetings can review day-to-day operational concerns as the trial progresses.

12. Reporting, Dissemination, and Impact

We will disseminate findings to academic audiences, service user/carer organisations, NHS Trusts, and policymakers, particularly Department of Health and Social Care and NHS England as follows:

i. A definitively tested and implementation-ready online psychoeducation and parenting intervention for parents with bipolar (IBPI)
ii. Papers on clinical and cost effectiveness of IBPI published in high-impact academic peer-reviewed journals (e.g., Lancet Psychiatry)
iii. Lay articles published through websites, magazines, conferences, and other publications produced by service user groups such as Bipolar UK, Mind, Depression Alliance, Young Minds, NSUN, and ReThink
iv. National and international conference presentation for academics, service users, carers. Outcomes will be disseminated to influential stakeholder groups including annual conferences of the medical and psychological colleges and associations. We will disseminate through service user and relatives' organisations including Bipolar UK, MIND and Rethink, and the Recovery Colleges covering two thirds of NHS Trusts in England and AHSNs
v. Project-specific website and Twitter feed will be updated throughout the programme, including links to lay and expert summaries of findings when published
vi. A full report for the NIHR HTA journal
vii. Summary of research findings for participants, including an accessible animation of the purpose and outcomes of the research, will be made freely available through project website and shared directly with participants by email with links

Impact of the study will, in the first instance, be on the 342 participants and their children in the study. The feasibility study indicated some potential benefits in both arms for participants. However, the clearest benefits were for those in the IBPI arm suggesting the potential for significant impact on child and parenting outcomes in the 171 participants and their families from that arm. We will work with all relevant stakeholders (clinical, academic, voluntary sector, service users and their relatives/friends) throughout the project to ensure IBPI is implementation-ready on completion. A problem with many online interventions is that they are often not successfully implemented (Bennion et al., 2017; Mohr, Riper & Schueller, 2018). To address this, we have partnered with LSCFT (NHS global digital exemplar) to host, promote and maintain the site post study with the support of Bipolar UK. LSCFT will be supported by other partners in Healthier Lancashire and South Cumbria Integrated Care System through their 'Our digital future' programme. Working with NHSX from the outset will also ensure IBPI's success in national dissemination and that it meets criteria for NHSX app library. This will ensure rapid national roll out of this intervention at completion of the study to benefit the many high-risk children and their parents in the UK. Our team have extensive links with NHS England and Health Education England, including with programmes to increase access to psychological support for people with bipolar. This intervention will be an important tool that clinicians can refer to as the sole tailored intervention to support parents with bipolar disorder and their children.

13. Financial Arrangements

This trial is funded by NIHR HTA.

14. Beneficiaries

The main direct beneficiaries of this research will be participants and their children, who will receive information and support they need. The intervention may improve the behavioural and emotional functioning of a vulnerable group of children, with benefits for their education and mental health including the potential to reduce risk of transition to severe mental health problems. The intervention may also benefit parents by increasing parenting confidence (as indicated in the feasibility study) and stabilise their mental health by adopting more stabilised routines. Other direct beneficiaries will be clinical staff, who will gain an increased awareness of support needs of parents with BD. There will also be the opportunity to explore the longer terms benefits of IBPI on future risks of bipolar, subject to further funding.

15. Declaration of Interest

Some members of the applicant team (SJ & FL) were also involved in the development and feasibility testing of IBPI. The applicant team are further developing the IBPI intervention as part of the study. Therefore, this study is not an independent evaluation.

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