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NHS
Health Research Authority

FULL/LONG TITLE OF THE STUDY
Understanding the Wellbeing and Support Needs of Partners of Parents with Bipolar (PPB)

SHORT STUDY TITLE / ACRONYM

Partners of Parents with Bipolar (PPB)

PROTOCOL VERSION NUMBER AND DATE

Version 2.1 27TH April 2026

RESEARCH REFERENCE NUMBERS

IRAS Number:	337057
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FUNDERS Number:	NIHR207571
INTERNAL REFERENCE Number:	A107335

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

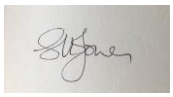
Signature:
.....

Date:
...../...../.....

Name (please print):
.....

Position:
.....

Chief Investigator:

Signature: 
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Date:
19/08/2025.

Name: (please print): Steven H Jones
.....

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KEY STUDY CONTACTS

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Committees	Study Steering Committee to be convened.

STUDY SUMMARY

Study Title	Understanding the Wellbeing and Support Needs of Partners of Parents with Bipolar (PPB)
Internal ref. no. (or short title)	PPB
Study Design	Mixed-methods: Survey/Qualitative Interviews/Toolkit Development
Study Participants	Partners of parents with bipolar.
Planned Size of Sample (if applicable)	Survey 150 Qualitative interviews 30 Social Care Toolkit Design: 10 partner carers (plus 10 social care professionals) Carer Toolkit Design: 10 lived experience experts (plus 10 social care professionals from social care toolkit recruitment)
Follow up duration (if applicable)	N/A
Planned Study Period	01/04/2025 – 31/12/2026 Survey 15 months Qualitative interviews 12 months Social Care Toolkit Development 6 months Carer Toolkit Design 6 months
Research Question/Aim(s)	Aim: To understand and address the wellbeing and support needs of partner carers of parents with bipolar.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**

providing funding and/or support in kind for this study)	
NIHR Research Programme for Social Care (NIHR207571).	£264,377 funding for this project.
CRN Funding?	
UK Research Innovation and Lancaster University Participatory Research Fund	£2,290 funding for additional arm

ROLE OF STUDY SPONSOR AND FUNDER

This project is sponsored by Lancaster University who will assume overall responsibility for the initiation and management of the project.

This project is funded by the NIHR Research Programme for Social Care (RPfSC) (NIHR207571). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care. The RPfSC reviewed the project's design during the grant application process and will have no further influence on the data analysis, interpretation, manuscript writing or dissemination of results.

The additional arm of this project has been funded by the UK Research Innovation and Lancaster University Participatory Research Fund. The views expressed are those of the author(s) and not necessarily those of the UKRI.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Steering Committee

In line with NIHR research governance guidance (https://www.nihr.ac.uk/documents/research-governanceguidelines/ 12154), a Study Steering Committee will meet at least annually to review study progress and conduct and consider substantial protocol amendments. The SSC will include an independent statistician, a PPI member, the CI, and RPfSC and sponsor representatives as observers.

Carer Reference Group

Sansom is carer lead, and grant holder on the project. He will lead monthly Carer Reference Group (CRG) meetings, supported by the RA who will help organise and minute these meetings. The CRG will meet monthly throughout the project. The CRG will be consulted on all study materials, such as participant information sheets and recruitment adverts. They will also be consulted on recruitment planning including optimising inclusiveness, planning for next steps after the completion of this study, development and implementation planning for the toolkit and contributing to outputs and dissemination from the study. Sansom is a member of the applicant team and will be present at operational and management meetings to represent the voice of the group at all stages of the process. A Public Involvement in Research Toolkit (PIRIT) has been adopted to track the changes made and learning gained from the insights of the CRG.

PROTOCOL CONTRIBUTORS

This protocol was created by the chief investigator, Prof Steven Jones, the study co-applicants, and Zoe Glossop and Lesley Sinclair.

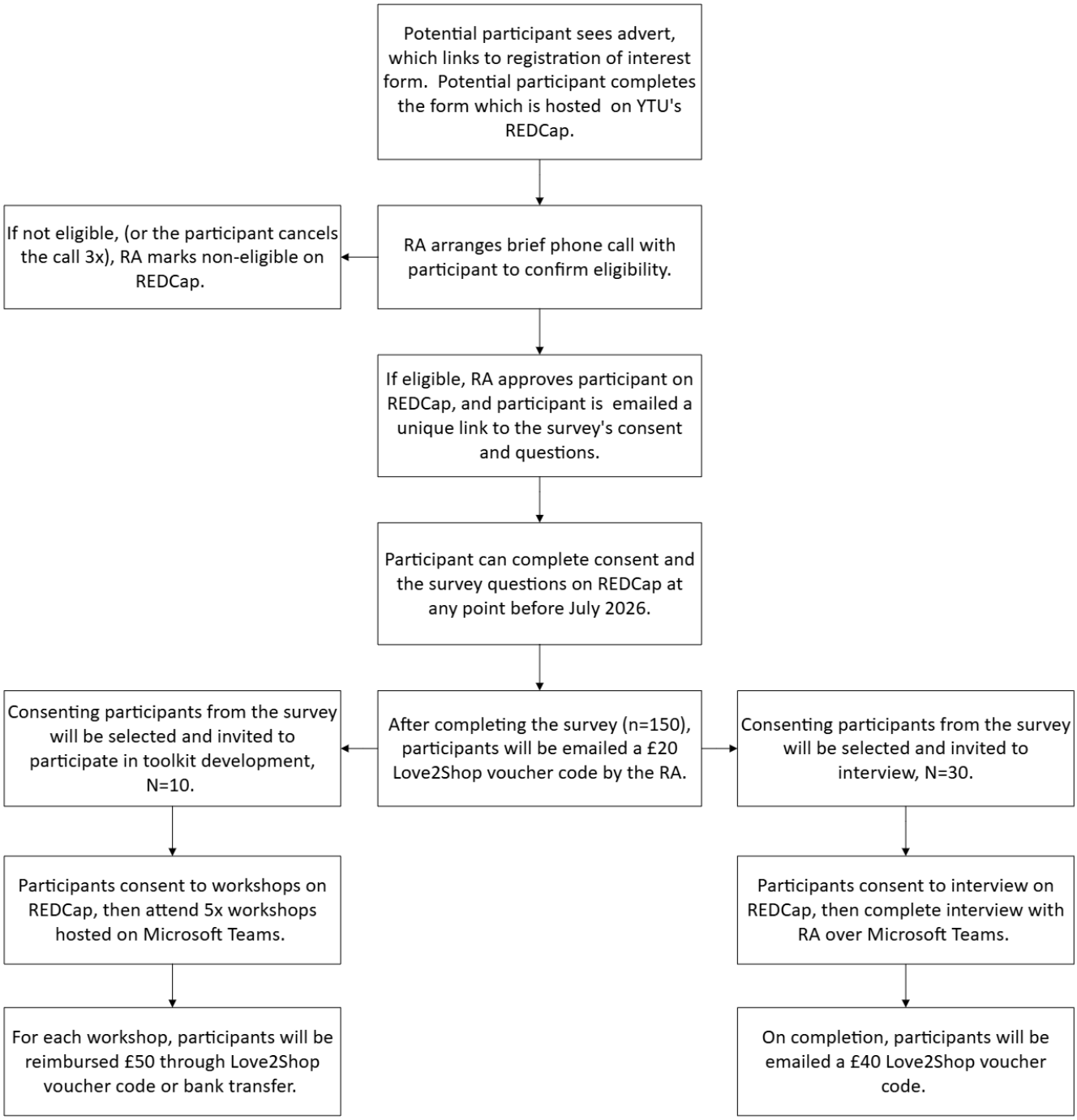
This project is sponsored by Lancaster University who will assume overall responsibility for the initiation and management of the project.

This project is funded by the NIHR Research Programme for Social Care (RPfSC) (NIHR207571). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care. The RPfSC reviewed the project's design during the grant application process and will have no further influence on the data analysis, interpretation, manuscript writing or dissemination of results.

The additional arm of this project has been funded by the UK Research Innovation and Lancaster University Participatory Research Fund. The views expressed are those of the author(s) and not necessarily those of the UKRI. The UKRI will have no further influence on the data analysis, interpretation, manuscript writing or dissemination of results.The recruitment process was designed in collaboration with the carer reference group. All study documentation (the survey questions, interview topic guide, advertising materials, and participant information sheets) has been reviewed and edited based on the feedback of the carer reference group.

KEY WORDS: Bipolar, parent, partner, carer, bipolar disorder, child

PARTNER CARERS FLOW CHART



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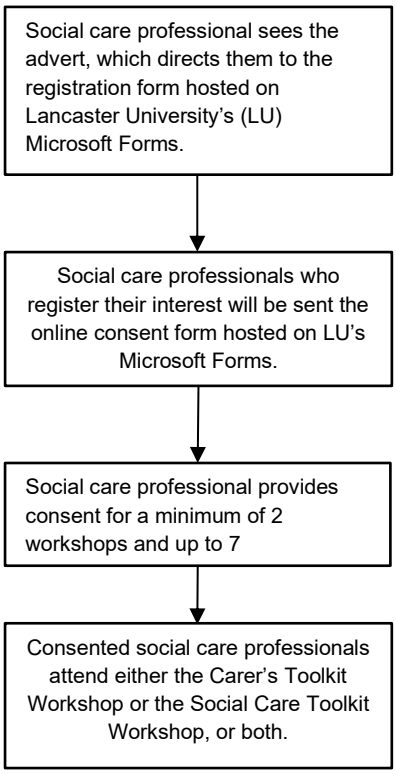
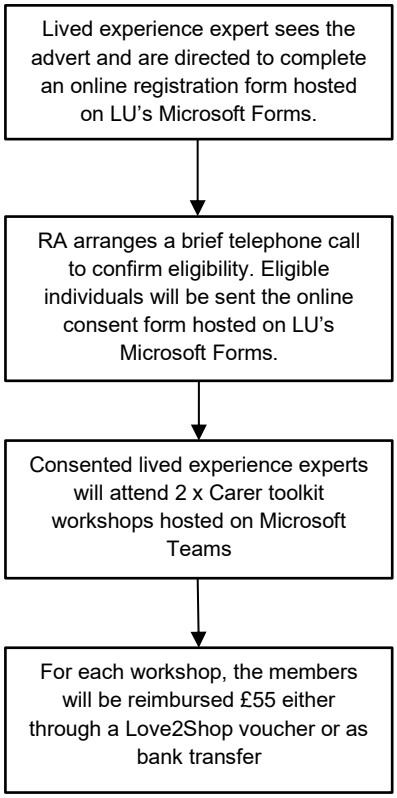
SOCIAL CARE PROFESSIONALS FLOWCHART



LIVED EXPERIENCE EXPERT (LEE) FLOWCHART



STUDY PROTOCOL

Understanding the Wellbeing and Support Needs of Partners of Parents with Bipolar (PPB)

1 BACKGROUND

We currently know little about the wellbeing and support needs of partner carers of parents with bipolar disorder (BD) despite their crucial care and support role. This research will focus on understanding partner carers' wellbeing and support needs as well as codesigning a social care tool for social workers to help address these. Since partner carers provide crucial care and support to their partners with bipolar, this research will focus on understanding what carers' needs are, how they want them addressed and how these are influenced by sociodemographic and clinical mental health factors in the family.

BD affects 2% of the population in the UK (McManus et al., 2016) with an expected annual cost in England by 2026 of £8.2 billion (McCrone et al., 2008), linked to limited access to effective care (McManus et al., 2016; NICE, 2014), delayed access to diagnosis of bipolar and poor continuity of care leading to worse outcomes (UK, 2022). Bipolar UK have highlighted that years lived with disability and burden of disease were 30% and 100% higher respectively for people with bipolar compared to people living with psychosis (UK, 2022). Much of this shortfall in support is met by carers, often partners of people with BD who play a crucial role in supporting wellbeing and recovery (Kargar et al., 2021; Lobban et al., 2020). Carers of people with bipolar experience significant burden including lower wellbeing and higher anxiety and depression (Pompili et al., 2014). Partners of parents with bipolar face dual challenges of supporting a parent with BD and their children, who are at elevated risk of mental health issues (Baruch et al., 2018; Lobban et al., 2020; Pompili et al., 2014; Venkataraman, 2011). There is evidence of relationship issues in partners of people with BD (Azorin et al., 2021; Namlı et al., 2023) and partner carers in particular experience poorer wellbeing than other carers (Sin et al., 2021). Furthermore, better relationship functioning is associated with improved personal recovery with people with bipolar (Wynter et al., 2021). However, risk of developing mental health disorders in children of parents with BD is increased when there are conflicts between parents (Azorin et al., 2021).

Despite the importance of partner carers, evidence of specific wellbeing and support needs of partners of parents with bipolar is lacking. There is also no evidence on whether they are accessing Care Act Assessments and, if they are, to what extent their needs are met. Furthermore, evidence about effective support for partners of people with BD is limited. Much research, and NICE guidance, has drawn on the experiences of parents of people with psychosis, which are unlikely to be directly comparable to the individuals who are partners of people with bipolar. This study will address these gaps by looking at the specific needs and experiences of partner carers and codesign actionable tools to address these. It will therefore inform more effective social care support for carers, with potential secondary benefits for their partner with bipolar and for their child(ren).

NICE guidance for BD highlights that carers should have a needs assessment and tailored education and support (NICE, 2014). In recognition of carers' crucial role, the Care Act 2014 was designed to support their rights. Local authorities were tasked with offering timely assessments of carer needs. Despite this, the majority of carers supporting someone with a mental health issue have not received a carer's assessment within six months of request (Matthews, 2017). Use of carer's assessments and support needs of partners of a parent with BD are yet to be systematically studied. In addition, research is lacking on the impact of caring on wellbeing in partners, and on how needs and wellbeing are impacted by social circumstances. A national representative study showed over 40% of individuals with bipolar were living with families (McManus et al., 2016). Understanding how to support carers has potential to benefit children's health and social care needs through improved parenting and support

(Coalition, 2023). The importance of this is recognised in the NHS Long Term plan (NHS, 2019) and emphasised by recent increases in mental health problems in children (Digital, 2022).

2 RATIONALE

This study will explore the social care support needs of partners of parents with BD, in a cost-effective manner, by carrying out the study alongside an existing national project evaluating a digital intervention for parents with bipolar disorder (Integrated Bipolar Parenting Intervention, IBPI: NIHR131483). It will benefit from the recruitment infrastructure of the IBPI study with additional recruitment through self-referral and our social care and third sector partners. This work will increase understanding of carers' wellbeing and support needs (including access to Care Act assessments) as well as the relationships between these and carer sociodemographic and clinical factors. This information will raise awareness of what carers need to help them flourish in these roles and improve social care practice in relation to these individuals.

3 THEORETICAL FRAMEWORK

The theoretical framework of this study is based in the important role of social and familial factors in the development of bipolar disorder (Miklowitz & Johnson, 2009). Having a parent with bipolar is a major predictor of an individual developing bipolar disorder (Duffy et al., 2014), which can be due to learned attitudes and cycles of behaviour within the family. Social Learning Theory (Bandura & Walters, 1977) suggests that children learn behaviours by observing and imitating their parents' actions, attitudes and responses to situations. Similarly, Coercion Theory (Patterson, 2015) describes a cycle of mutual reinforcement where negative interactions between parent and child escalate and reinforce negative behaviours. For example, a child may react with anger to a parent's request, leading to stress and anger from the parent, which intensifies as the cycle continues. As a result, children learn a coercive relationship pattern which transfers over into interactions beyond their immediate family, such as with teachers at school.

Another relevant construct is expressed emotion, which includes critical, hostile and/or emotionally overinvolved attitudes towards the person with bipolar. Families and couples with high expressed emotion are characterized by bidirectional patterns of conflict which escalate and become increasingly personal and are associated with higher relapse rates for people with bipolar (Yan et al., 2004). In contrast, families with low expressed emotion can interrupt these escalations sooner (Simoneau et al., 1998) and are more likely to maintain supportive relationships.

Therefore, partners of parents with bipolar play a key role within the family. As both a caregiver to the person with bipolar and a parent of the child, the partner plays a central role in moderating family dynamics. They can provide stable and supportive interactions which may mitigate coercive cycles, which in turn supports the child's development. However, partners themselves may require support to fulfil this role. From a cognitive behavioural theory perspective, providing parents with personalised support they need in the challenging context of being a parent and having a partner with bipolar is likely to optimise their wellbeing and their ability to parent well. Therefore, this study aims to explore how partners can be better supported to improve family functioning and promote positive developmental outcomes for children. This study aims to better inform effective services for families with bipolar.

4 RESEARCH QUESTION/AIM(S)

The aim of this study is to understand and address the wellbeing and support needs of partner carers of parents with bipolar. Towards this aim, we will pursue the following objectives:

Objectives:

4.1 Objectives

Work Package 1 (WP1): Online survey

- To determine levels of and factors associated with partner carer wellbeing.
- To determine partner carers' needs for support including experiences of Care Act assessments.

Work Package 2 (WP2): Qualitative interviews

- To understand in depth the experiences of partner carers with respect to their wellbeing and support needs and how they intersect.

Work Package 3 (WP3): Co-design

a) To develop a framework for a toolkit specifically for partner carers, which will be further refined alongside the development of the social care toolkit in the next stage of the project

b) To create an impactful toolkit on identifying and addressing partner carers' needs for frontline social care professionals.

4.2 Outcomes

WP1 will address these objectives using survey methodology and a combination of bespoke questions and standardised questionnaires.

WP2 will address this aim through semi-structured qualitative interviews sampled for diversity of carer experience from participants in WP1.

WP3a will address this objective through coproduction workshops, which will develop a framework for a carer-specific toolkit informed by WP1 and 2. WP3b will address this objective through coproduction and implementation of a social care toolkit with versions for social care professionals and partner carers informed by WP1, 2, and WP3a.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

5.1 Study Design

We will use a partially mixed sequential equal status design (Leech & Onwuegbuzie, 2009) with both a quantitative survey and qualitative interviews. These will explore rates of use and experiences of carer's assessments, as well as support needs and wellbeing.

By collecting sociodemographic data from the partner carers, it will be possible to explore what factors most clearly influence wellbeing and needs. A qualitative phase will then be used to refine our understanding of these experiences in depth (Fetters et al., 2013) and explore what help and support carers feel they need. The final phase of the study will be conducted in two parts. Phase 3a of the study will focus on the initial development of a toolkit framework in collaboration with people with lived experience and social care professionals, specifically for partner carers, informed by learning from the first two phases. Phase 3b will be to coproduce an impactful and actionable toolkit for social care

professionals to support partner carers in practice, informed by learning from the first two phases and the first part of the third phase. This final phase will also include further refinement of the carer toolkit alongside the development of the social care toolkit.

5.1.1 Relationship of this project to IBPI trial

The IBPI trial is an ongoing randomised controlled clinical trial testing the clinical and cost effectiveness of a digital intervention for parents with bipolar disorder, who have a child aged between 4-11. Both studies share a chief investigator (SJ) and another senior grant holder (FL). Recruitment for the IBPI trial is continuing until the end of November 2025 with follow up assessment until November 2026. The RA employed in the current study will be collocated with the IBPI team and meet regularly with the CI and trial manager for operational planning. However, recruitment will not be reliant on the IBPI trial, as outlined below.

5.2 Measures

5.2.1 Survey

Bespoke questions on social demographic information of the partner carer and their family, including the partner carer's age, gender, ethnicity, education, geographical location, and duration of caring. The survey will also ask about their partner's and their child's sociodemographic information, including age, gender, ethnicity and diagnoses and number of psychiatric admissions. These questions will be included to help characterise the sample, which will be used during interview sampling, as well as to explore the relationships between these factors and experiences of wellbeing, depression, and anxiety.

Bespoke questions on knowledge and experiences of Carer's assessments. These structured questions will explore whether participants know what a carer's assessment is and how to access one, and whether they have had one. If so, questions will ask to what extent it met their needs for support and their satisfaction with the process. Overall, this will help us to understand the proportion of this group who are accessing these assessments and what impact they have had.

Bespoke questions on what support the participant feels they need, with open-ended response textboxes. Responses to these questions can be explored further during the interview and toolkit development.

Standardised measures of wellbeing (Tennant et al., 2007), anxiety(Löwe et al., 2008), depression(Kroenke et al., 2001), carer wellbeing and support (Quirk et al., 2012) and Loneliness, using the ONS-recommended harmonised standard measure (ONS, 2018). Using standardised measures will help us to compare this sample with groups from other research. Also, these are valued outcomes based on our PPI work so exploring the factors that influence these will be an important aspect of the research.

5.2.2 Interview

Qualitative interviews will provide in depth information about partner carer's personal perspectives on their wellbeing and support needs and any help they have had with these or would want. The topic guide for the interviews will be co-developed with the CRG and will also be informed by participant responses to the survey. Participants will be interviewed either by secure live video call or phone, according to their preference.

Interviews will be semi-structured, with the topic guide used for guidance but allowing the participants to explore specific areas of importance to them. Participants will be interviewed by trained research staff and trained social worker interns. All interviews will be recorded and transcribed.

5.2.3 Codesign

We recognise that we have two cohorts within the study that, due to their experience of caring for individuals with bipolar disorder or other mental health conditions, can be classed as lived experience experts. The two cohorts we note are:

(i) partner carers who are partners of parents with bipolar recruited from those who complete the survey, and

(ii) lived experience representatives recruited through our partner organisations specifically for the carer toolkit workshops

Whilst we recognise that both cohorts are experts by experience, for clarity, we will not refer to the partner carers as lived experience experts for the purposes of this protocol; they will continue to be referred to as partner carers throughout the study protocol.

The co-design workshops for the Social Care Toolkit with partner carers will be held separately from those with social care professionals. For the Carer Toolkit co-design workshops, the lived experience experts will attend workshops separately from the social care professionals.

For WP3a, two workshops (2 hours each) will be held with lived experience experts recruited through partner organisations, facilitated by the carer lead with support from the RA as part of WP3a. Additional workshops will also be conducted as needed with the social care professionals. For WP3b, over 6 months, there will be a series of 5 half day co-production workshops, with an external facilitator. Representation from social care providers, the third sector, and commissioners will form the social care professional group. Partner carers recruited from those completed the survey will form the partner carers group. . Engaging a range of stakeholders will help ensure that the final toolkit is accessible, relevant and fit for purpose for commissioning to impact frontline practice.

Based on feedback from the CRG members, the partner carers and social care professional groups will meet in separate workshops (a and b respectively) as partner carers may feel more open to share their views in a group consisting of their peers. The same format will be used for the co-design sessions with lived experience experts.

Social care professionals will have the option to attend either the Carer Toolkit workshop, the Social Care Toolkit workshop, or both, with a minimum requirement of participation in two workshops.

5.3 Data Collection

Partner carers will complete all survey measures online directly in REDCap (Research Electronic Data Capture), hosted by York Trials Unit. A subset of people completing the survey will take part in the qualitative interviews, which will take place online over Microsoft Teams. A subset of survey participants will also be invited to take part in the co-design sessions associated with the development of a Social Care toolkit. Details regarding the participant selection are provided in the 7.2.1 and 7.3.1 sections within this protocol.

Lived experience experts will take part in the two workshops associated with the development of the Carer Toolkit. Social care professionals will take part in up to seven workshops as part of the WP3

arm of the study, with an option to attend either the Carer Toolkit workshops, Social Care Toolkit workshops or both. Both co-design workshops will take place online via Microsoft Teams.

5.4 Data Analysis

5.4.1 Survey

All data from the survey will be summarised descriptively using means and standard deviations (or medians and interquartile ranges) for continuous variables and counts and percentages for categorical variables. Linear (e.g., carer wellbeing) or logistic regression (e.g., access to support) models will be used to explore relationships between outcomes and sociodemographic factors. Open text data will be thematically summarised.

5.4.2 Interview

Qualitative data will be thematically analysed, with a coding frame and themes developed iteratively and collaboratively by an analysis group including carers with lived experience and social care perspectives supported by the CRG. The framework will help organise data round key areas of need highlighted by participants, and the interpretation of findings will be developed to produce clear recommendations for the design of the toolkit.

5.4.3 Codesign

Learning from each workshop will be captured from an inductive review of data to identify key toolkit development and implementation themes. The core research group will use this information to iteratively develop toolkit content in partnership with professional and lived experience knowledge groups. Information from both WP3a and WP3b workshops will be compared to identify the differing themes emerging from the different workshops. A live illustrator may be present at some of the co-design workshops to summarise discussions and provide immediate feedback to attendees.

6 STUDY SETTING

This study will take place online in the UK and will involve multiple cohorts: i) Partner carers ii) Social care professionals, and iii) Lived experience experts.

Partner carers will be recruited from Local Authority and NHS settings across the UK, as well as self-referral. They will also be recruited through our partner organisations, including Bipolar UK, LSCFT and Lancashire and Cumbria ICB (and partner ICBs), third sector organisations and online research platforms. LSCFT will operate as a Participant Identification Centre (PIC) alongside GP surgeries within the Research Delivery Network (RDN), which will also operate as PICs. Social care professionals involved in the co-design workshops will be recruited from LSCFT as well as third sector organisations and local authorities. The lived experience experts will be recruited through our partner organisations, including Bipolar UK, LSCFT and Lancashire and Cumbria ICB (and partner ICBs).

The study is UK-specific because parenting practises may differ between countries and cultures, and the study focuses on partner carers' experiences of Carer's Assessments, which are unique to the UK.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria for the partner carer cohort

- Age >= 18 years
- Partner of a parent with bipolar

- Living with partner and child
- Parent with bipolar has at least one child, up to 18 years old, for whom they have parental responsibility
- Living in the UK

Inclusion criteria for social care professionals

- Age >= 18 years
- Living in the UK
- Participant must also meet one of the following criteria:
  - Currently employed in a mental health or social care professional role relevant to supporting carers or people with serious mental illness (e.g. social work, health, commissioning, third-sector roles).
  - Have professional experience working with carers and/or people living with serious mental health issues.

Inclusion criteria for the lived experience expert cohort

- Age >= 18 years
- Living in the UK
- Participants must also meet at least one of the following criteria:
  - Have lived experience of being a carer of someone with bipolar
  - Is a partner of someone with bipolar

7.1.2 Exclusion criteria

Exclusion criteria for partner carer cohort

Participants will be excluded if they:

- Live outside of the UK.
- Live separately from their partner or child.

Exclusion criteria for the lived experience expert cohort

- Live outside of the UK
- Are a member of the current CRG (PPB advisory panel) group

There are no exclusion criteria for the social care professionals.

What is meant by partner and parent?

This study is designed to be as inclusive as possible for different family types. The term “partner” refers to any cohabiting romantic relationship, such as a spouse, boyfriend or girlfriend. The term “parent” refers to anyone with parental responsibilities for a child aged under 18, including having biological children, step-children and adopted children. Participants are eligible if they report that their partner has bipolar disorder; they live with their partner, and they have a shared parental responsibility for a child.

Examples of eligible participants for the partner carer cohort

Below are fictional examples of people who would be eligible to participate in the study:

- John (aged 34) has lived with his girlfriend, Lara (aged 35), and his girlfriend's son, for 3 years. Lara's son is aged 5 and John is his stepdad. Lara was diagnosed with bipolar disorder last year, and John has been looking after both Lara and their son.
  John would be eligible to participate.

- Elizabeth (aged 49) has been married to her husband, Michael (aged 52), for 18 years. Michael was diagnosed with bipolar disorder 6 years ago. They have two daughters together, aged 14 and 17. Both Elizabeth and Michael live together and parent their two daughters together.
  Elizabeth would be eligible to participate.

- Josh (32) and Daniel (35) have lived together for 7 years. Daniel was diagnosed with bipolar disorder 15 years ago. Together, they adopted a child 3 years ago who is now aged 4. Both share parental responsibilities.
  Josh would be eligible to participate.

Inclusion Criteria Rationale for the partner carer cohort

These criteria were chosen to ensure that the study was focused on partners of parents with bipolar, who still have non-adult children, whilst also being as inclusive as possible. The focus is on partners because these are the main carers of people living with bipolar (Berk et al., 2013), as opposed to carers of people with other mental health issues such as psychosis who tend to be the adult patient's parents (Jansen et al., 2015). The experiences of partners of parents with BD are likely to be distinct from the carers of people with other mental health issues too, because of the relapsing and recurring pattern of extreme moods. As parents with BD can move from highly competent to in need of substantial support repeatedly, the experiences of these partners are different from those of carers who are supporting people with other complex, yet potentially more stable, mental health challenges, such as psychosis.

People with a partner with BD navigate an ever-shifting balance, as their caring demands shift alongside their partner's mood episodes (Clancy, 2016). Certain features of mania, such as hypersexuality leading to infidelity, or impulsive spending leading to budgeting issues for the whole family, can cause specific concerns for partners. This is reflected in the high rates of relationship breakdown and burden in this group (Namlı et al., 2023).

The inclusion criteria of having a child up to 18 years old was decided to target families who are still actively parenting non-adult children. While there has been previous research into the experiences of partners of people with BD, the needs of partners who are intermittently caring for an adult with bipolar, as well as caring for a child, have not yet been explored. Furthermore, bipolar disorder runs in families and has a peak onset at around age 19 – 20 (Solmi et al., 2022). Having both a partner and a child with bipolar disorder would lead to specific additional issues for carers that would impede a more general understanding of parent and partner issues [8]. The criteria of living with their partner and in the UK is to ensure a clear picture of carer partner experiences relevant to the UK context.

Inclusion Criteria Rationale for Social Care Professionals Group

Following conversations with our grant holders and interns trained in social care and social work, it was felt that we needed to be more inclusive with our language and use the term social care professionals instead of social workers. This encompasses people who have knowledge and expertise in working with people with BD as well as their partners, carers and families.

Description of the Lived Experience Group

The lived experience expert group will include adults who have experience of caring for someone with bipolar and/or who are partners of someone with bipolar disorder. Participants may meet one or more of these criteria. We are including people with caring experience more broadly because they may still have relevant insights into caring roles, the challenges of caring, and support needs, even if they are not specifically partners of someone with bipolar. The lived experience expert group will be different from the CRG, which is the lived experience advisory panel for the current PPB study.

7.2 Sampling

7.2.1 Size of sample

We will recruit 150 partner carers for WP1. This sample size would allow us to estimate proportions of access to Carers Assessments to within a margin of error of <=8% and continuous measures to within a standard error of <=4 points (Price et al., 2005). CH, as director of York Trials Unit, calculated the sample size for the purpose stated. Of the 342 parent participants in the IBPI trial, recruiting 150 partner carers in the analysis would represent 44% of the IBPI sample. We will also, as noted above, supplement recruitment from outside of the trial to achieve the required sample size through social media and third sector/community recruitment.

For WP2 around 30 partner carers from those who complete the survey will be recruited for qualitative interviews to ensure data sufficiency (Vasileiou et al., 2018).

For WP3a, 10 lived experience experts will be recruited for the codesign workshops.

For WP3b around 10 partner carers from those who complete the survey will be recruited for the co-design workshops

10 social care professionals will be recruited for the professional arm of the co-design workshops for WP3a and WP3b.

7.2.2 Sampling technique

The survey will use snowball sampling by recruiting in part through the ongoing IBPI trial. Advertisements will be shared with existing IBPI trial participants so they can share the information with their partners about the PPB project. As partner carers can be a hard-to-reach group, recruiting through the IBPI trial will help us to contact participants' partner carers who may not otherwise be engaged with Bipolar services or charities.

Convenience sampling will be used through social media recruitment and sharing advertisements through our partners Bipolar UK and LSCFT. Survey participants will be recruited on a first come first served basis.

For the interviews and co-design groups, participants from the survey will be purposively sampled for demographic diversity across gender, ethnicity, same-sex partners, and geographical spread; as well as

whether carers have accessed a carer's assessment or not. Only partner carers consenting to be contacted about an interview or the codesign groups in the survey in WP1 will be invited.

We will continue to use convenience sampling for the recruitment of the lived experience cohort for WP3a by circulating the advertisements through LSCFT, Bipolar UK, and the PPI networks at Lancaster University. We will also advertise the opportunity on the NIHR's people in research site if needed.

Professionals for the co-design sessions (WP3a and WP3b) will be recruited by using purposive sampling, supported by convenience recruitment through existing networks. The advertisement will be shared with LSCFT's social care professionals by the project's social care lead, who is based at LSCFT. The project's social care lead will also support recruitment by circulating the opportunity to third sector organisations and local authorities. Professionals involved in the Capacity and Capability Building Internship Programme, which is part of the project, will also be invited to participate.

7.3 Recruitment

Partners of parents with bipolar disorder will be recruited in a variety of ways that reflect the importance of understanding social and health care in an integrated way, consistent with NHS and wider government policy.

7.3.1 Sample identification

Survey

Firstly, we will offer the opportunity to carers who are partners of parents with bipolar in the current IBPI study. Participants in the IBPI study are recruited until November 2025 with final follow-ups in November 2026, so we are confident that participants recruited will still be contactable when this study starts. This has been designed to recruit nationally from as diverse a population as possible.

Secondly, we will recruit carers through targeted social media advertisements, managed with Nativve Health Research (https://www.healthresearch.study/). Nativve are a digital recruitment service who specialise in using targeted ad campaigns on various social media platforms (including Facebook, Google, Youtube, Twitter) to recruit participants for health and social care research studies. We are currently working with Nativve for recruitment on the IBPI trial, which has led to 693 registrations of interest.

Thirdly, we will advertise the survey online and in-person through our partner organizations (Bipolar UK, Lancashire and South Cumbria Foundation Trust (LSCFT), and Lancashire and Cumbria ICB and partner ICBs). Bipolar UK has good national reach to underserved groups including ethnic minority groups and people who identify as non-binary. LSCFT will act as recruitment site. Participants will also be identified through GP surgeries within the Research Delivery Network (RDN), which will be added as Participant Identification Centres (PICs) for the study; GP PICs will undertake the same activities as other PIC sites. In addition, we will advertise via third sector organisations and recruitment platforms such as Research For Future and People in Research, following the same recruitment procedures used for Bipolar UK. Finally, as per suggestions from our CRG, we will also advertise the study in libraries, school noticeboards, and other community settings. These places were identified as places where partners of people with BD, who are also parents of young children, or their partners are most likely to be.

In each case interested partner carers will use an online link to access information about the study, decide if they want to take part and register their interest. On receipt of the registration of interest, the RA will arrange a short call over telephone or Microsoft Teams with the participant to confirm eligibility for the study, and to provide an opportunity for the participant to ask any questions. This will both provide support to all participants including anyone who feels less comfortable with technology and will also minimise the risk of bad actors or bots accessing the survey, consistent with previous research. Following this telephone call, the RA will mark the participant as eligible on REDCap and send a personalised survey link to the participant via email, who will then be able to provide consent and subsequently complete the survey.

Interview

Thirty survey participants will be recruited for interviews. Participants will be selected from the pool of participants who completed the survey, and who consented to be contacted for the interviews during the survey. The RA will view participants' survey responses on REDCap. Participants will be sampled for demographic diversity across gender, ethnicity, same-sex partners, and geographical spread; as well as whether carers have accessed a carer's assessment or not.

Codesign

For the carer toolkit codesign workshop as part of WP3a, ten lived experience experts will be recruited by advertising online through Bipolar UK, through LSCFT, through the PPI networks at Lancaster University and also through the NIHR's people in research site, if needed. Lived experience experts who register their interest in the study will be contacted by the RA to arrange a screening call, during which their eligibility will be confirmed over the phone. During the screening calls, participants will also have the opportunity to ask any questions about the study.

Ten survey participants, who are partners of parents with bipolar disorder, will be recruited for codesign sessions. These participants will constitute the partner carer group. Participants will be selected from the pool of participants who completed the survey, and who consented to be contacted for the codesign sessions during the survey. The RA will view participants' survey responses on REDCap. Participants will be sampled for demographic diversity across gender, ethnicity, same-sex partners and geographical spread; as well as whether carers have accessed a carer's assessment or not. For both social care and carer toolkit workshops, sessions with professionals will be help separately from partner carers and lived experience expert groups. The social care professionals for both series of workshops will be recruited from across our partner organisations. Recruitment will be supported by the project's social care lead at LSCFT, who will share the opportunity with social care professionals within LSCFT and through established links with third-sector organisations and local authorities. Professionals involved in the Capacity and Capability Building Internship Programme, which forms part of the project, will also be invited to take part

7.3.2 Informed Consent

We will seek valid informed consent from participants online.

Partner carers will have the chance to learn more about the study through the PIS, which will be linked to on the registration of interest form (hosted on York Trial Unit's REDCap) as well as on the consent form (hosted on York Trial Unit's REDCap). Following the British Psychological Society's guidance (2021), the PIS will include clear information about data rights, withdrawal rights, and the risks and benefits of taking part. The PIS will include the Health Research Authority's GDPR transparency wording (HRA, 2025). Participants will be able to ask questions during a brief screening call with the RA, which will be arranged after the participant registers their interest.

After the participant's eligibility has been confirmed during the screening call, and any questions have been answered, they will be emailed a link to the consent form hosted on REDCap. As the survey will be hosted online, from December 2025 to December 2026, participants will have a maximum of one year to decide whether or not to take part. The first consent form will be consent to take part in the survey. A link to the PIS will be included at the top of the consent form. After completing consent, the same REDCap form will include all the survey questions. During the survey, there will be two options to consent to be contacted about an interview and about the co-design workshops. Partner carers who consent to be contacted will be emailed by the RA with the interview-specific and/or codesign-specific PIS, as well as a link to the interview-specific and/or co-design specific consent forms, which will also be hosted on REDCap. To confirm ongoing consent, verbal consent will be obtained from participants before the interviews and at the start of each co-design session.

The social care professionals will have the chance to learn more about the study through the PIS, which will be linked to the registration form hosted on Lancaster University's Microsoft Forms. The PIS will include clear information about data rights, withdrawal rights, and the risks and benefits of taking part. Social care professionals will then be contacted to provide informed consent, hosted on Lancaster University's Microsoft Forms, for participation in up to seven co-design workshops, which include both the Carer's Toolkit and Social Care Toolkit workshops, with a minimum requirement of participation in two workshops. To confirm their ongoing consent, they will also be asked to provide verbal consent before each session, which will be documented in the workshop notes.

The lived experience expert cohort will register their interest in the study after reading the PIS, which will be linked to the registration form hosted on Lancaster University's MS Forms. This document will also have detailed information about their data and withdrawal rights risks, and the benefits of taking part. The RA will arrange a brief screening call with the participant who registers their interest to confirm eligibility and offer participants the chance to ask any questions they might have. Eligible people will be contacted to provide consent for participation in the Carer Toolkit workshop (hosted on Lancaster University's MS Forms). They will also be asked to provide verbal consent before each session begins to confirm ongoing consent to take part, which will be documented in the workshop notes.

If participants would rather read the PIS on paper, we will provide the option to post the PIS to their address.

7.3.3 Participant Withdrawal

Participants will be able to withdraw from the survey before completing it, by closing the survey and not completing it, and/or by emailing the research team. Responses which are incomplete (i.e. where the participant does not formally 'submit' the survey online by the end of the survey period (by July 2026) will be considered as withdrawals and removed from the dataset. Participants with incomplete responses before the end of the survey period will be emailed reminders to complete the survey 1, 2 and 3 weeks after starting it. Participants will also be able to withdraw completely and opt-out of receiving reminder emails, by emailing the research team.

After completing the survey, participants will be able to withdraw by contacting the research team to request that their data is removed. To do this, they will need to provide their unique email address. If the data has already been anonymized for analysis, withdrawal may not be possible, in which case the data will be retained and this will be explained to the participant.

For the qualitative interviews participants can ask for their interview data to be removed up to one week after completing the interview, after which the data will have been transcribed and anonymised and incorporated into themes.

For co-design workshops, the participants will be able to withdraw by contacting the research team before the workshops. If participants wish for a statement they have shared to be removed from the workshop notes, they must raise this during the workshop so it can be removed at the time. As data will be recorded as anonymised notes, once data collection is complete, it will not be possible to remove individual contributions.

7.3.4 Participant Payments

After completing the survey, participants will be reimbursed with a £20 shopping voucher. This will be sent over email via REDCap and managed by the RA.

After completing the interview, participants will be reimbursed with a £40 shopping voucher. This will be emailed by the RA.

After taking part in each codesign session, participants will be reimbursed with a £50 shopping voucher over email or bank transfer depending on participant preference. The professional knowledge group will not receive payments as participation in the sessions will be considered as part of their regular role.

The lived experience experts involved in the study, will be paid in line with the NIHR national guidelines for participatory research (NIHR Public Contributor Reward and Recognition Policy | NIHR).

7.3.5 Participant Timeline

Potential participants will be identified through social workers, clinicians Bipolar UK or self-referral. They are directed to the study registration of interest site hosted on REDCap. On completion of this registration of interest the RA then arranges a screening call to check participant eligibility and answer any questions. Eligible participants are confirmed by the RA on REDCap. The REDCap system then automatically emails the participant a unique link to the Survey PIS and consent form. After completion of the consent form, participants then take the survey after which they are emailed a voucher in recognition of their time in completing it. Participants who record their willingness to be approached about the qualitative and/or toolkit development phases of the study will be selected by the RA according to sampling requirements and invited to these phases over email. The RA will email links to the relevant PIS and consent forms through REDCap. Before the interview, the participant will receive a broad summary of the questions over email, although they will not need to do any preparation for the interview.

Social care professionals will be identified through multiple channels within LSCFT. They will be directed to complete a registration of interest form hosted on Lancaster University's Microsoft Forms. Once this information is received, the RA will send the PIS and consent forms (also hosted on Microsoft Forms). Professionals will consent to take part in a minimum of two workshops and will be invited to attend either the Carer Toolkit workshop, the Social Care Toolkit workshop, or both, depending on their preference. To confirm ongoing consent, verbal consent will also be obtained at the start of each workshop, which will be documented in the workshop notes.

Lived experience experts will be identified through Bipolar UK or LSCFT and will be directed to complete a registration of interest form hosted on Lancaster University's Microsoft Forms. The RA will arrange a brief screening call with the participant who registers their interest to confirm eligibility and offer participants the chance to ask any questions they might have. Eligible people will be contacted to provide consent for participation in the Carer Toolkit workshop (hosted on Lancaster University's MS Forms). Consented lived experience experts will be invited to attend the Carer Toolkit workshops. To confirm ongoing consent, verbal consent will also be obtained at the start of each workshop, which will be documented in the workshop notes.

7.4 End of Study Definition

The end of the study is defined as the completion of data gathering across all three work packages: the survey, the interviews, and the co-design workshops.

8 ETHICAL AND REGULATORY CONSIDERATIONS

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 Practice (GCP), information security training, and assessing risk. York Trials Unit will oversee all quantitative data collection, storage, and management and ensure that this is anonymous and secure and consistent with the Data Protection Act (2018). The study will be registered with the Centre for Open Science https://www.cos.io/initiatives/prereg

8.1 Assessment and management of risk

8.1 Potential Risks and Burdens

The main risks identified are relating to:

1. Online study design
2. Recruitment
3. Confidentiality and data management
4. Participant distress

1. Online study design

The study will be conducted online, through online survey software and video calling software. Conducting the study online means that more people will be able to take part and are not limited by geographical or time based restraints; participants will be able to complete the survey at a convenient time for them. Participation in an online study requires access to the internet and a certain level of computer literacy, therefore some people may be unable to take part. However, we expect this number to be low. The Office for National Statistics found that in 2020, 96% of households in Great Britain had internet access. Furthermore, we have budgeted some funds to help pay for participants' internet costs if people need it.

One potential problem with online surveys is that they are susceptible to bad actors, especially if the survey includes a financial reward. "Bad actors" can include people completing the survey without attention, as well as people running bots to complete surveys automatically, in order to receive a voucher. To prevent this, we have carefully included safeguards in accessing the survey, based on our research team's past experiences running online surveys as well as recommendations from the

published literature (Storozuk et al., 2020). Potential participants will first register their interest through an online form, and then the RA will arrange a 5-minute screening call. The call serves to check the participant's eligibility, and answer any questions they may have, and also to deter bad actors or bots. After this, each participant will have a unique version of the survey link. This means that each participant can only complete the survey once (and receive one voucher), and cannot distribute the survey link themselves.

Another potential concern with online surveys is data security. The survey will be hosted on York Trials Unit's REDCap, which is a secure software designed to be used in research.

2. Recruitment

We aim to recruit widely, through:

- advertisements in the ongoing IBPI trial's newsletter

- targeted social media advertisements with a social media company Nativve

- social media advertisements shared by the research team's accounts

- potential participants identified by social workers at LSCFT

- advertisements in our team's research interest networks, including Spectrum Connect and Bipolar UK's mailing lists.

Using such a varied approach should enable us to recruit to the 150-participant target.

3. Confidentiality and Data Management

Personal data collected during the survey, interviews and co-design process will remain strictly confidential and will not be shared with anyone outside of the research team. Data will be stored online using password-protected access. For qualitative interviews, all transcripts will be pseudonymised and the participant's personal information will be removed from the transcript. The transcript or any quotes published will not be linkable to the participant. The transcripts will be linked to participant data using an identification number stored separately from other data. 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, in which case we will contact relevant emergency services (with the participant's prior consent, established during the consenting process for the study and at the beginning of the interview). Personal data will be stored for up to 1 year after the study ends it may be accessed to inform participants of the findings of this research and/or to assess the research quality. Anonymised study data will be archived for a minimum of 10 years on Lancaster University's database PURE, in line with Lancaster University's policy on data storage.

4. Participant Distress

Participating in the survey could lead to distress when participants reflect on their challenges of supporting their partner, as well as their own mental health. To reduce the potential for this, we developed the survey questions in collaboration with our Carer Reference Group. The feedback from the CRG was to include more explanation as to why we are asking each set of questions, which we have included, and to remove a question on the carer's hospitalisation history.

In case participants do experience distress, we have included "Resources for dealing with distress" on the participant information sheet. This list includes charities like Mind and Bipolar UK, as well as the

Samaritans and 111 if people require more urgent help. We have also included parenting and caring specific resources, based on feedback from the CRG.

There is also a risk that participants become distressed during the interview as sensitive topics may be discussed. Interviews will be conducted by an experienced researcher who will offer the participant breaks and remind them that they do not need to answer every question and remind them of their right to withdraw. The interview PIS also includes the resources detailed above.

Based on the study team's previous experiences working with carers of people with mental health issues, we do not expect it to be likely that participants will disclose a significant risk such as suicidality or harm to others. In the unlikely event a significant risk to the participant or to others does arise, the RA will signpost the participant to resources on the PIS including the Samaritans, and/or to speak with their GP, and/or to access other local services. Our CRG strongly recommended this approach, rather than asking for the participants' own GP details as this was considered too intrusive.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from an NHS REC for the study protocol, informed consent forms, participant information sheets, and other relevant documents e.g. advertisements. Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site. All correspondence with the REC will be retained. The Chief Investigator will produce the annual reports as required and will notify the REC of the end of the study.

An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review & Compliance

Before any participants are recruited, the Chief Investigator or designee will ensure that appropriate approvals from participating organisations are in place. A collaboration agreement with all collaborating organisations will be developed.

Amendments

Amendment tools and amended documents will be shared by the study team with the sponsor for approval. In instances where the sponsor decides that the amendment is significant, the study team will share the amendment through the Integrated Research Application System (IRAS) with the nominated research ethics committee (REC), for consideration. For non-substantial amendments, the amendment will be uploaded to IRAS with notifications sent to the national coordinating review bodies (Health Research Authority (HRA), Health and Care Research Wales (HCRW), and the National Coordinating Function). R&D governance officers at participating research sites and Participant Identification Centres (PICs) will be notified of approved amendments either automatically through IRAS or by the study team where applicable. They will have 35 days from the time of notification of approval to object to substantial amendments. Amended documents will be version controlled and incrementally numbered and dated to demonstrate a new version. A version log will also be kept by the trial team, detailing the amendment in which a document was updated. This ensures a version control. Tracked and clean versions of amended protocols will be uploaded to the Research Awards Lifecycle Management System (REALMS) when approved.

8.3 Peer review

This study was reviewed during the funding application by the Research Programme for Social Care funding committee. The committee comprised social care experts, methodologists, public and practitioner members. Committee members review all outline and full applications and make funding recommendations based on the quality of applications, with support from expert peer reviewers. Members of NIHR committees are required to declare any interests which conflict, or may be considered to conflict, with NIHR business, or may be perceived as influencing decisions made in the course of their work within NIHR programmes. All members are asked to complete the Register of Interest form (annually), which is intended to capture long term predictable interests that could be perceived to lead to conflicts of interest. These and other interests are judged on a case-by-case basis at individual meetings.

8.4 Patient & Public Involvement

Sansom is carer lead, and grant holder on the project. He will lead monthly Carer Reference Group (CRG) meetings, supported by the RA who will help organise and minute these meetings. The CRG will meet monthly throughout the project. The CRG will be consulted on all study materials, such as participant information sheets and recruitment adverts. They will also be consulted on recruitment planning including optimising inclusiveness, planning for next steps after the completion of this study, development and implementation planning for the toolkit and contributing to outputs and dissemination from the study. Sansom is a member of the applicant team and will be present at operational and management meetings to represent the voice of the group at all stages of the process. A Public Involvement in Research Toolkit (PIRIT) has been adopted to track the changes made and learning gained from the insights of the CRG.

At the beginning of the project our carer lead will recruit eight people to the CRG. We will recruit people with lived experience as a partner of a parent with bipolar from a range of locations with representation of different genders, sexual orientation and ethnicity.
Carers will be paid in line with NIHR guidance for their time spent preparing for and attending the CRG meetings. Carers will be paid via bank transfer or voucher depending on their preference. Bank transfers will be paid through LSCFT and vouchers will be paid through Lancaster University.

8.5 Protocol compliance

Minor, unintentional protocol deviations can happen, however the trial team will ensure a thorough knowledge and understanding of the protocol prior to working on the study to mitigate against this. Should any protocol deviations occur they will be reported to the Chief Investigator and Sponsor immediately. Relevant Sponsor paperwork will be completed and filed appropriately. Any recommendations by the sponsor or learnings from the deviation will be actioned by the trial team and will be recorded on the Sponsor's deviation paperwork.

Repeated protocol deviations will not occur. In unlikely circumstances where repeated protocol deviations have occurred then the same process will be followed for other deviations. The sponsor however may classify this as a serious breach and may initiate an audit. Following an audit relevant regulatory bodies including the nominated research ethics committee may be informed of the protocol violation by the sponsor.

All protocol violations and deviations will also be reported at the Study Steering Committee (TSC).

8.6 Data protection and participant confidentiality

All electronic study data will be stored in accordance with GCP guidelines for the duration of the study. Data will be securely stored on password protected Onedrive systems at Lancaster University and the cloud-hosted REDCap system at the University of York. All personal data will be stored in accordance

with the General Data Protection Regulation and Data Protection Act 2018. A data management plan will be developed in collaboration with Lancaster University's and University of York's data management teams.

8.6.1 Lancaster University

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.

As per Lancaster University's Research Data Management policy (www.lancaster.ac.uk/library/research-data-management/research-data-management-policy) - anonymised research data will be retained for a minimum 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, University of York REDCap system). 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://portal.lancaster.ac.uk/ask/download?document=/media/lancaster-university/content-assets/documents/library/rdm/RDMPolicy2023.pdf).

8.6.2 University of York

Survey data will be collected and held securely on the cloud-hosted REDCap server. Access to the study interface will be restricted to named authorised individuals granted user rights by a REDCap administrator at YTU. All work will be conducted following the University of York's data protection policy which is publicly available (https://www.york.ac.uk/records-management/dp/).

8.7 Indemnity

Lancaster University holds appropriate indemnity cover which includes but is not limited to Public Liability, Professional Indemnity and Employers Liability Insurance. If participants are harmed whilst taking part in the study as a result of negligence by Lancaster University or its staff members, they may have grounds for legal action and should obtain independent legal advice. Non-negligent harm is not covered in any case, and any claims that arise may be referred to the insurance provider for assessment. If participants are harmed as a result of the negligent conduct of NHS staff supporting this study, then they may have grounds for legal action under the NHS Indemnity Scheme and should consult their own independent legal advice-any claims may be referred to the provider for review.

8.8 Access to the final study dataset

Lancaster University will manage the final study datasets.

Lancaster University will store anonymised data on the study's OneDrive for potential further analysis during the study period. After the study period, the data will be deleted from OneDrive. The anonymised .csv survey dataset and codebook will be stored on the Lancaster University PURE repository after publication of research outputs at the end of the research, for a minimum of 10 years. This will be available for research purposes under controlled access, after approval from the CI, to ensure that the intended use of the data is in line with good practice principles.

The interview recordings will be deleted during the study period, after transcription is complete. After the study period, transcripts will be archived on PURE but these will not be accessible for the public or other researchers due to the potentially identifying nature of the content. A collection of anonymised quotes will be made available on request from the CI, which will also be uploaded to PURE. The anonymised fieldnotes from the codesign sessions will also be stored on PURE and will be available on request with approval from the CI.

The results of this research will be shared via conferences, peer-reviewed journal articles, training materials, and through our website.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

Lancaster University will own the data arising from the study. After study completion, the data will be analysed and outputs prepared. All outputs will include acknowledgement to the NIHR Research Programme for Social Care funding. Outputs will include open access publications in high impact journals, as well as presentations at clinical and carer conferences. We will also create plain English summaries and circulate them through our third sector links and social media and host a project specific website and X feed. Another key output from this work will be the carer support toolkit designed to impact frontline practice. Taken together these outputs will provide vital information on the needs and experiences of partner carers of parents with bipolar in the UK for the first time. Information on study progress will be shared with participants via the study website and regular email newsletters.

Our project partners will facilitate sharing of the study outcomes through their blogs, e-magazines and websites. We will also work with NHS England to incorporate learning from the study in existing training programmes such as the national ‘Understanding bipolar and psychosis course’ for all NHS staff which our team run for NHSE. The social worker interns will also help share learning and promote the toolkit to peers. Cowley-Sharp, Cleece and Lloyd-Evans will build on implementation of the toolkit through the regional ICB to incorporate into wider social worker training and CPD.

Our outputs will be developed and promoted with the support of our third sector and social care collaborators and integrated into training for social care practitioners. We have support from our ICB to ensure the toolkit has immediate impact and will provide a model for national rollout drawing on our teams’ established links with DHSC. Our findings will also be shared widely across academic and social care stakeholders as well as voluntary sector, the public and clinical groups.

The outputs of the project will be free to access including the toolkit. A potential implementation barrier is lack of support from key stakeholders for improving social care for partner carers. We have already established relationships with our regional Trust, ICB and local authority partners who confirm the need for this work and their support for it. We will work with them at each stage of the project to ensure the pathway to impact regionally to provide a model for national implementation on study completion.
The primary impacts of the research will be to improve understanding of the needs and experiences of partner carers of parents with bipolar and to provide a codesign toolkit for social workers to improve the

social care experiences of this group. By improving support for carer partners there is the potential to also positively impact on their children and partners social and health outcomes.

9.2 Authorship eligibility guidelines and any intended use of professional writers

The ICMJE (International Committee of Medical Journal Editors) guidelines on authorship will be followed (https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html).

Authorship will be based on the following 4 criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or reviewing it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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11. APPENDICES

11.1 Appendix 1- Required documentation

Local documentation required prior to initiating a participating site:

- CVs of the research team
- Patient Information Sheet (PIS) on headed paper
- Study advertising materials

11.2 Appendix 2 – Schedule of Procedures

	Registration	Months 3-16	Months 9-16	Months 14-19
Expression of interest	✓			
Initial Screening	✓			
Informed consent	✓			
Survey				
Bespoke questions on social demographic information of the carer and their family		✓		
Bespoke questions on knowledge and experiences of Carer's assessments		✓		
Bespoke questions on what support the participant feels they need		✓		
Qualitative				
Semi-structured interviews			✓	

Toolkit Development				
Codesign workshops				✓

13.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	1.1	06/11/2025	Ragin John	Addition of end of study definition
2	2.0	11/02/2026	Eirian Kerry and Ragin John	• Addition of a study arm, • Clarified the terminology used to describe each participant cohort. • Updated the term “Social Worker Toolkit” to “Social Care Toolkit” throughout the document. • Replaced the term ‘social workers’ with ‘social care professionals’ to broaden the eligible professional cohort. • Expanded and clarified the identification, recruitment, and consent procedures for social care professionals forming the Professional Knowledge Expert group. • Expanded and clarified the identification, recruitment, and consent procedures for the Lived Experience Expert cohort
3	2.1	27/04/2026	Ragin John and Eirian Kerry	• Clarified the inclusion criteria for lived experience experts by amending the wording from “have lived experience of being a carer” to “have lived experience of being a carer of someone with bipolar disorder.” • Clarified the recruitment details in the protocol to include GP surgeries as Participant Identification Sites, following the approval of amendment NSA02 (26.03.2026).

				• Clarified in the recruitment section that third sector organisations and established research recruitment platforms, such as Research for the Future and People in Research. will be used to recruit partner carers.

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.