

PARTICIPANT INFORMATION SHEET for IBPI TRIAL

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

We would like to invite you to take part in a research study exploring the effectiveness of an online intervention for parents with bipolar disorder. Before you decide whether you'd like to take part, we want to explain why we are doing this research and what it will involve. Please read the following information and discuss with others if you wish. You may download this sheet and print it off to read at your own convenience. Please ask us if there is anything that's unclear, or if you'd like further information after reading the information sheet (contact details at the end).

What is IBPI?

IBPI stands for the 'Integrated Bipolar Parenting Intervention'. This is a digital resource with guidance on parenting for those who experience bipolar disorder. It includes 9 modules, covering areas such as 'managing mood changes' and 'helping your child learn new skills'. The website contains videos and interactive exercises, as well as information on bipolar disorder and parenting support. The IBPI website will be accessible 24 hours a day, 7 days a week, and can be accessed on a computer, a tablet or mobile phone (either through the website or through an app).

What is the study about?

Our team of researchers, clinicians, and parents with bipolar disorder have created the IBPI tool with the aim of helping people with bipolar with their parenting. We hope this will improve their children's behavioural and emotional outcomes, improve the parents' mood and confidence, and improve overall family functioning. Our aim is to make the IBPI site available for parents with bipolar across the UK.

However, first we have to see if it works and if it is cost effective. To do this, the current study will test the effectiveness of IBPI on reducing child behavioural and emotional problems and parent stress and anxiety, and increasing parents' confidence and family functioning, as well as exploring the costs involved in delivering the intervention.

Who is the study for?

We are looking for parents with bipolar disorder, who have a child aged 4-11 years old, and live in the UK. Participants will also need access to a computer, tablet, or mobile phone, as well as internet access to take part. If you want to take part but have issues with the cost of internet access, please let us know as we may be able to help with this.

Why have I been approached?

You have been approached because we think that you could make a valuable contribution to this research study. Sharing your experiences with us will help us to determine how helpful this intervention is for parents with bipolar.

Do I have to take part?

No. Participation is completely voluntary – it is up to you.

Can I change my mind and withdraw from the study?

If you decide to take part and then later change your mind, you have the right to withdraw from the study at any time without giving a reason (although you'll be invited to give a reason so we can learn from your

experience). If you withdraw from the study, we will stop collecting data from you and your access to the IBPI site will end. Any data we have collected from you prior to withdrawing cannot be retracted and may still be used in analysis.

You will also be able to partially withdraw. This means you could take part in the study and complete some questionnaires but not all of them. To withdraw, partially or fully, you can email a member of our research team (contact details at the end of this form).

If you decide not to take part or withdraw at any time, this will not affect any services or care that you or your child may be receiving, or your ability to take part in future research.

What will happen if I do take part?

If you decide you would like to take part, you will need to first register your interest on the trial information website. We'll ask you to give us multiple forms of contact (email, phone number, and postal address) so that we can contact you for screening, follow-up assessments, and to confirm your identity at each assessment point. You will then be invited to have an initial screening interview with a member of the research team. This is a brief check to see if you are likely to be eligible for the study, and so you can give us your consent to take part online. At this time, you will be provided with this participation information sheet and the consent form. Please take as long as you need to read them, you are welcome to also ask us any questions. If you have an initial screening at a recruitment event, you are welcome to read through this document and provide your consent on the day if you wish to, but you are also welcome to take this information home and consider participation over time if that's preferable for you.

If you decide you're happy to take part, you will need to return the signed consent form to us and provide the details of your GP or care co-ordinator (please see the next section for more information on why we'll take these contact details and what we may use them for). You will be allowed as much time as you need to decide if you want to complete and return these forms, but we will follow up after 2 weeks to check if you have questions

about the forms or about participation in general. We will follow up with you a maximum of 3 times via email. However, if you decide after this time you would like to take part and submit your details, the links will remain active until the recruitment window closes.

Once your signed consent form and GP/care co-ordinator details have been received, you will be invited to an eligibility check. This is an interview with a member of the research team to ensure your experiences of bipolar disorder meet the criteria for this study (this interview may include the following assessments: SCID-5; Structured Clinical Interview for DSM-5). The eligibility check will happen over the phone or via video call (whichever you'd prefer) and will be recorded, just in case we need to check with another team member that your experiences are appropriate for the study. The content of the recording will not be analysed or published, and will be deleted after the study. You'll receive £40 for taking part in the eligibility check and the initial assessment. If you are deemed ineligible after your eligibility check, you will still receive £40 but you won't be required to complete an assessment.

If your bipolar experiences meet the criteria of the study, we will then ask you to complete a few questionnaires about your child's behaviour and emotions, as well as your own mood, parenting stress and confidence, and family functioning.

You will then be randomly assigned by a computer (this is like a coin toss with a 50/50 chance of either result) to either receive the IBPI online intervention plus your current treatment, or to follow your current treatment. If you are allocated to receive the IBPI intervention, you will be sent a link to the IBPI website and login details to access the website. It is very important that you do not share these details with anyone. The study relies on comparing outcomes for people who have received access to IBPI with those who have not. It is therefore very important that people don't move between these groups, and that people not taking part in the study don't have access to IBPI.

Your use of the website will be monitored by the trial team in order to learn more about how participants are engaging with IBPI, but please note that any usage data we see will be anonymous and cannot be traced back to you personally. We will look at things such as how often the site is accessed, which pages are visited most, and how these usage patterns relate to outcomes for participants. This will be done by linking patterns of use with the data collected from questionnaires (which will also be anonymous). At no time will personally identifiable information be accessed for this purpose.

To examine how helpful IBPI is for parents, we will ask you to complete the same online questionnaires that you completed at the beginning of the study. This will happen 24 weeks after you joined the study, and then again 48 weeks after you joined. These include questions about your child's behaviour and emotions, your own mood, parenting stress and confidence, and family functioning.

Previous studies have found that people sometimes struggle to remember their moods from longer than 3 months ago. To assist with this, you will be given a mood diary. This will include prompts to briefly reflect on your mood symptoms over the previous 4 weeks. You can record your mood by selecting the tick boxes in the mood diary that best reflect your experiences. These diaries are for personal use only; at no point will researchers request to see these. We will ask that you use your diary every 4 weeks throughout the trial so we can get a clear picture of your moods. If you forget every now and then we'll understand, but we ask that you please try to record your moods at least once every 12 weeks. You will be able use the mood diary to remember your mood experiences when filling in the assessments after 24 and 48 weeks. After the study has been completed, you can dispose of the diary.

It is really important that you try to complete the 24- and 48- week follow-up assessments, regardless of which group you are allocated to. Even if you stop using the IBPI website, your insights are still important to us so please do complete the assessments when requested. This will ensure we

have all the information we need to properly test whether the website is beneficial. If you struggle to complete any of the questionnaires, you can request a support call with a member of the research team who will be able to help. You will be paid £10 as a thank you for your time when you complete the questionnaires at 24 and 48 weeks. This is a total of £20.

If you are assigned to the group that has access to the IBPI online intervention, you might also be invited to participate in a feedback interview later on in the trial. The purpose of the feedback interview is to help us get a better understanding of how you used the website, what you found helpful and unhelpful, and whether it had a lasting impact on you. In total, up to 20 participants who have had access to the intervention website will be invited to participate in a feedback interview. If you're selected and agree to participate, you'll receive £40 for your time. This interview is separate from, and in addition to, the initial screening and eligibility check that all participants will complete. The feedback interview will be recorded, transcribed, and analysed to help us understand more about how people experience the website. Recordings will be securely destroyed following completion of transcription. All transcripts will be pseudonymised, which means that all of your personal information will be removed from the transcript. As such, neither the feedback interview transcript nor any quotes published can be linked to you in any way.

We may periodically send participants newsletters with updates about the trial progress and reminders to log into the website.

After the study ends, participants who were in the group without access the IBPI website will be provided access to it.

In what instances might we have to share information with other services?

We will use the details you provide for your GP or care co-ordinator to let them know you are taking part in the IBPI study. It is important that we make your GP or care co-ordinator aware of your participation in this

healthcare study so they are fully informed about what services and support you are accessing.

We will only contact your GP or care co-ordinator again if an immediate and serious risk of harm to yourself or others is identified by the research team. If this happens, we are required to break confidentiality and inform the appropriate emergency services (e.g. medical, police or social services) in an emergency, in order to protect the welfare of both you and those around you, including your child/children.

Which interviews will be recorded?

There are a total of three interviews in this study, although most people will only have two. The first is the initial screening interview, the second is the eligibility check, and the third is the feedback interview, but not all participants will be invited to a feedback interview.

The initial screening interview will not be recorded.

The second interview, the eligibility check, happens after the initial screening and helps us to confirm your experiences of bipolar and check that you are eligible for the study. This will be recorded just in case we need to check your eligibility with another research team member, but it will not be transcribed or analysed as part of the research.

The final interview is the feedback interview, which will take place approximately 11 months after you start the trial. Approximately 30 people from the group that received access to the IBPI website will be invited to this. No one from the group that did not have access to the intervention will be invited to a feedback interview. These will be recorded and transcribed, with all personally identifiable information removed. The anonymous data will then be analysed and will contribute to our research conclusions.

What will happen to my data?

We will never share your personal details with anyone outside the research team. The only exception to this is if there is a clinical or safeguarding issue, where an immediate and serious risk of harm to yourself or others is

identified by the research team. If this happens, the researcher is required to break confidentiality and inform the appropriate emergency services (e.g. medical, police or social services) as an emergency, as well as your GP or care co-ordinator.

Your GP or care co-ordinator details will be stored by Lancaster University. We will only hold this information whilst you in the study. Once you have finished engaging with study activities, this data will be securely destroyed.

Both the eligibility check and feedback interviews will be recorded, the initial screening interview will not be. The eligibility check recording will be securely destroyed as soon you receive a decision from the trial team regarding whether or not you are eligible for the study. In addition to being recorded, the feedback interview will also be transcribed. Once transcribed, the recording will be securely destroyed. In the transcript, your name will be replaced with a pseudonym and all personal information will be removed to ensure your anonymity is protected.

All data from all participants will be combined together prior to analysis, and any data used in the write up of the study will not be identifiable to any participant.

The data collected for this study, including pseudonymized transcripts from the feedback interviews, will be stored securely on encrypted, password-protected computers and on password-protected databases managed by Lancaster University. Some data will also be stored securely on York Trial's unit cloud-hosted REDCap server, managed by the University of York.

Only the researchers conducting this study will have access to any of this data. Your anonymised data may be stored for up to 10 years after the study, in line with both Lancaster University's and the University of York's policies on data storage. You will not be personally identifiable from your data.

Lancaster University will be the data controller for any personal information collected as part of this study. Under the GDPR you have certain rights

when personal data is collected about you. You have the right to access any personal data held about you, to object to the processing of your personal information, to rectify personal data if it is inaccurate, the right to have data about you erased and, depending on the circumstances, the right to data portability. Please be aware that many of these rights are not absolute and only apply in certain circumstances.

If you would like to know more about your rights in relation to your personal data, please speak to the researcher on your particular study. For further information about how Lancaster University processes personal data for research purposes and your data rights please visit our webpage:

www.lancaster.ac.uk/research/data-protection

Please be aware that many of these rights are not absolute and due to the university's lawful basis for processing data for research, some of your data rights are affected. For example, you will not be able to withdraw your information after it has been combined with other participant's information.

During the study, we need to manage your records in specific ways for the research to be reliable. This means we won't be able to let you see change some of the data we hold about you. Please use the link above to learn more, or contact the research team with any questions.

What will happen to the results?

If you participate in this study, you will be provided with a summary of the findings at the end. The findings will be presented at academic and mental health conferences and events. The findings will also be published in mental health journals and other publications, with the aim of reaching a wide audience of mental health professionals, service users, and other researchers. You will not be personally identifiable from the published results.

What are the benefits of taking part?

There may be potential benefits from using IBPI for children's emotional and behavioural problems, as well as for parenting outcomes. There is a

chance you find no direct benefit to yourself, however we hope you find the information in the study helpful and interesting to engage with, and we hope you finish the study feeling like you've made an important contribution to research aimed at improving support for parents with bipolar disorder and their families.

Will I be paid for taking part?

As a thank you for your time, you'll be paid £10 at each of the two follow-up assessment points. You'll also be paid £40 for completing the eligibility check and the initial assessment at the start of the trial. This is a total of £60. If you are selected for the feedback interview, you will receive a further £40.

Please note that as the IBPI trial is only open to UK participants, payments can only be made to UK bank accounts in your own name.

What are the risks of taking part?

There are no direct risks anticipated with participating in this study. If you do experience any distress in relation to any aspect of the research, please request a support call from a member of the research team by emailing ibpi@lancaster.ac.uk or use the contacts indicated at the end of this document.

Lancaster University Insurance cover

Lancaster University holds appropriate indemnity cover which includes but is not limited to Public Liability, Professional Indemnity and Employers Liability Insurance. If you are harmed whilst taking part in this study as a result of negligence by Lancaster University or its staff members, you may have grounds for legal action and should obtain independent legal advice. Non-negligent harm is not covered, and any claims that arise may be referred to the insurance provider for assessment. Should you require more information on the indemnity cover that Lancaster University holds, please contact the research team on the contact details at the end of this Participant Information Sheet.

Who has reviewed the project?

This study has been reviewed and approved by the West Midlands – Solihull Research Ethics Committee (REC).

What do I do if something goes wrong?

It is unlikely that you will be harmed by participating in this study. However, if you wish to raise concerns or make a complaint about any aspect of this study, then you can contact either of the following people:

Dr Laura Machin (not a member of the research team)
Chair for the Ethics Committee, Faculty of Health and Medicine
Lancaster University
Phone: +44 1524 594973 Email: l.machin@lancaster.ac.uk

Professor Steven Jones (Chief Investigator of the study)
The Spectrum Centre for Mental Health Research
Faculty of Health and Medicine (Division of Health Research)
Lancaster University
Email: s.jones7@lancaster.ac.uk

Thank you for taking the time to read this participant information sheet

Contact details of research team

If you have any questions or would like more information about the study, please get in contact with a member of our research team on ibpi@lancaster.ac.uk

Or you can contact the Trial Manager directly:

Lucy Cryle

Phone: 07977 609378

Email: l.cryle@lancaster.ac.uk

FURTHER RESOURCES

Resources for Dealing with Distress

Should you feel distressed during the study, the following resources may be helpful for you.

- Mind – provides information, training, and support for people with mental health problems and their families: <https://www.mind.org.uk/>
- Rethink Mental Illness – provides information, training and support for people with mental health problems and their families: <https://www.rethink.org/>
- Bipolar UK – provides information and support for people with bipolar, including support groups and support lines: <https://www.bipolaruk.org/>
- Campaign Against Living Miserably – provides online information and telephone/online chat support to people experiencing distress: <https://www.thecalmzone.net/>

- The Hub of Hope – provides details of mental health support services in your area (UK only): <https://hubofhope.co.uk/>
- Patient Advice and Liaison Service (PALS) – provide a point of contact for patients, their families and their carers to offer confidential advice, support and information on health-related matters: [What is PALS \(Patient Advice and Liaison Service\)? - NHS \(www.nhs.uk\)](#)

If you need more urgent help and are already in contact with mental health services, please contact them directly. If you are not in contact with mental health services, the following might be helpful:

- Your usual GP practice
- Your local out of hours GP or Accident and Emergency. Please visit www.nhs.uk if you're unsure where to find these services
- If you are unsure of what help you need, call 111 for the NHS telephone advice service
- For someone to talk to over the phone, call Samaritans on 116 123 or email jo@samaritans.org
- If you feel there is a serious and immediate risk, please call the emergency services on 999

Resources for finding out more about data protection and storage

You can find out more about how we use your information in the following ways:

- By visiting www.hra.nhs.uk/information-about-patients
- By asking one of the research team
- By sending an email to the Data Protection Officer at the organisation sponsoring this study, Lancaster University: information-governance@lancaster.ac.uk
- Further information about how your data will be used, including Lancaster University's research data management policy, can be found here: <https://www.lancaster.ac.uk/library/research-data-management/research-data-management-policy/>