Plan Overview

A Data Management Plan created using DMPonline

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

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Template: Lancaster Data Management Plan Template

Project abstract:

Aim

We aim to assess whether providing an online parenting tool for parents who have bipolar disorder (BD) helps reduce stress and improves confidence in their parenting and in turn supports their children to have better emotional and behavioural outcomes.

Background

Parents with BD experience fluctuations in mood and have concerns that these mood variations impact on their ability to parent consistently. Inconsistent parenting can lead to emotional and behavioural challenges in their children, with children more likely to experience anxiety and other mental health difficulties in adolescence and early adulthood if unsupported.

Parents are often reluctant to access support due to stigma. Accessible, flexible, and confidential online parenting support is a way to provide tailored support to parents with BD. The current project aims to assess whether the integrated bipolar parenting intervention (IBPI) is clinically and cost effective.

Design and method

Parents with BD with a child aged 4-11 years old in the UK will be recruited through primary and secondary care, third sector organisations and social media. 284 participants will be randomly allocated either to a group that receives the online intervention or a treatment as usual (control) group. Questionnaires will be completed by participants, about themselves and their child at baseline, 24 and 48 weeks after being randomised into the study. All participants in the intervention group will be invited to complete a survey of up to 13 questions asking them about their website use and views of the website. A sample of the participants having completed the feedback survey (between 15-20) will be interviewed to learn their views of the intervention and its usability.

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Copyright information:

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

Data Collection

- **Will you be using existing datasets, creating new, or a combination of both?**
- **What is the content and coverage of these existing and new datasets?**
- **What is the type, format and amount/size of the data?**
- **How will you manage routine organisational activity, such as file naming, version control and folder structure?**
- **How will the data be collected or created?**

Overview

This study will generate new datasets across six different areas; personal data, demographic data, clinical and health economic outcome survey data, IBPI website usage data, mixed methods feedback survey data and feedback interview data. We will reuse existing datasets capturing indices of deprivation from the four nations' .gov websites which are freely available. We will use these datasets to calculate the levels of deprivation in the population using participant postcodes.

Personal Data

Personal data will be inputted directly by participants onto Microsoft Forms. This includes participant's name, email address, postal address, phone number and study referral method. Participants' email addresses will be transferred manually to REDCap by study researchers, so that outcome surveys and reminders can be sent automatically by the REDCap system.

Participants postcodes to determine Indices of Deprivation, collected through MS Forms and confirmed verbally during eligibility interviews will be transferred to an .xls document saved on a secure Teams channel, accessible only to the research team.

Updated contact details, consent to take part in the full trial, and to be invited to take part in the qualitative aspect of the work will be electronically captured directly onto REDCap by participants themselves or by a study researcher.

GP details will also be input directly by participants onto MS Forms after they have been screened as initially eligible to take part in the study.

Consent forms will contain personal data as participants are asked to enter their name and signature when completing the online forms in REDCap.

Personal data collected will equate to approximately 4.5GB.

Eligibility Data

Data from the eligibility interview will be collected by Lancaster University research team during live interviews recorded on a Teams video/voice call. Data collected during the interviews will be input by the researcher to an online version of the Structured Clinical Interview for DSM-5 (SCID-5) scoring sheet in .xls format. The scoring sheet will be reviewed by the Chief Investigator to determine eligibility; eligibility data will be recorded on REDCap by the research team following this review. Data pertaining to each participant's diagnosis obtained from the scoring sheet will be transferred to a separate .xls document by Lancaster University research team and will be stored on a secure Teams channel, accessible only to the research team. All data collected from eligibility interviews will equate to approximately 70 MB.

Outcome Survey Data

Clinical outcome data, health economic data and demographic data will be collected directly onto REDCap. It will be managed, pseudonymised and analysed at York Trials Unit (YTU). We have stated that the data is pseudonymised as the data includes demographic information of a distinct population (parents who have bipolar disorder with a child between 4-11year olds); the data therefore cannot be described as fully anonymised. The final data set (comprising of the demographic, clinical and health outcome data) will be a pseudonymised file, in .csv format., and this will equate to approximately 10 GB.

IBPI website usage data

The IBPI website usage data will be collected by Lancaster University's Information Technology and Partnering and Innovation team. This includes the details of which participants have accessed the intervention, the number of times they have accessed the intervention, including details of specific content accessed, and dates of access. The data is expected to be approximately 10.5 MB.

This data will be downloaded in .csv format and saved onto a Lancaster Teams channel set up for the website usage data only. This is to ensure that no blinded team members have access to this data; only the trial manager, qualitative researcher and the trial statisticians at YTU will have access to this secure Teams channel.

Feedback Survey

Consent forms and feedback survey responses recording a participant's use and opinion of the intervention will be collected and stored on Lancaster University's Qualtrics. The pseudonymised files will be downloaded in .csv format for analysis by Lancaster University research team and saved securely on Teams. This data will equate to approximately 1GB of data.

Feedback Interviews

Consent to take part in the interviews to obtain data on participants' use and opinions of the intervention will be inputted directly by participants on Lancaster University's Qualtrics system. The feedback interviews will be conducted by a researcher employed at Lancaster University. This means that interviews will be conducted over phone or video call using Lancaster

University's Microsoft Teams and complying with Lancaster University's data protection policies. The interviews will be recorded. Each recording is expected to be up to 400MB and will be saved on the trial's Teams Channel. Recordings will be transcribed within a week of the interview. The transcriber will sign a confidentiality agreement before commencing work on the project. Once transcribed, the transcriptions will be checked against the recordings for accuracy, viewed by the qualitative researcher to produce initial reflections, and then securely deleted. Participants will be given a second participant number which will be different to the participant number they have in the trial, ensuring that their qualitative feedback is not linked with their outcome survey data collected in the full trial. The pseudonymised transcriptions will then be uploaded to Lancaster University's NVivo software where the qualitative researcher will code the data into codes and sub-themes.

Version Control

The trial manager and the research team will be responsible for version control of approved documents, with non-substantive amendments being updated by 0.1 for each amendment. Documents updated with substantial changes will have their version renamed by 1.0 for each amendment. Any changes to documents will be communicated to the team, with links to updated documents. The research team will be advised not to download documents to their personal devices but instead use live links to folders to ensure they are using the most recent versions of all documents. Previous versions of documents will be moved to a folder named 'Archived' which will sit alongside current files; this will ensure there is a record of previous versions of documents and that there is a distinction between current approved and older versions.

Documentation and Metadata

Documentation

- **What project level documentation will be produced and shared, describing the overall context of the research project?**
- **What data level documentation will be produced and shared, describing the format of and variables within the research project?**
- **How will the documentation support publishing and discovery?**
- **How will the documentation support sharing and re-use?**
- **Will any of the documentation become a citable output alongside the dataset?**

Metadata

- **What machine readable documentation and information will be produced and shared, describing the dataset itself? e.g. Date of creation, provenance, licensing, versioning...**
- **Which aspects of this will be automatically generated by the repository you choose to deposit the dataset in? e.g. persistent identifier, access method, publisher, creator names...**
- **How will the metadata support making the dataset findable and citable?**

Documentation

The protocol paper was published before the end of the recruitment window. This documented the aims, outcomes, methods and planned data analysis for the study. This is available via the UK's Clinical Study Registry. Up to date participant information sheets will also be available on the clinical study registration page of the trial.

The study protocol will be freely available on the funders trial webpage and will be updated following each ethically approved amendment to the protocol.

Outcome Survey Data

A statistical analysis plan (SAP) and Health Economic Analysis Plan (HEAP) will accompany the outcome survey .csv dataset that will be produced. The SAP and HEAP will be in .pdf format and will include information of the scoring of each measure and details of the analysis of the applicable outcome survey data.

A codebook will be downloaded from REDCap.

A brief description of the background of the study will also be produced as a .pdf file. The outcome survey dataset will include the dates of completion and participant demographics as associated metadata. The .csv codebook and .csv dataset will be archived in Lancaster University's PURE system.

The archived dataset and codebook on PURE will have metadata including: a DOI, the names and roles of the main researchers, contact information of the CI, and ethical approval information. This metadata will increase the findability of the dataset as the DOI can be used to cite the PURE record from other published articles. It will also increase findability because the dataset will be linked to the main researchers' and CI's PURE profiles.

The archived dataset, codebook, SAP and HEAP will be available for others to access upon approval by the CI (or delegated individual) and YTU's statistician.

IBPI Website Usage Data

The Analysing and Measuring Usage and Engagement Data (AMUsED) framework will accompany the IBPI website usage data.

Feedback survey data

A copy of the feedback survey will accompany the feedback survey dataset.

Feedback interview data

A copy of the interview topic guide will accompany the approved selected interview quotes upon archiving.

Metadata

Outcome Survey Data

The available metadata will include participant demographic data, clinical diagnosis and referral method.

Feedback Interviews

Metadata will include the date of the interview as associated metadata.

Storage, Backup and Security

Use this guide from ISS File Storage, Sharing and Collaboration Services to:

- **select appropriate university systems**
- **request additional storage**
- **find correct language and terminology to describe the services and workflows you will use**

Use this guide from ISS Security of Data and Information to:

- **find technical details on access and storage**
- **select methods of sharing securely with external partners**
- **consider secure disposal**

Use this guide from ISS Storing information in the cloud to:

- **select appropriate university and external systems**

Use this guide from ISS Information Classifications to:

- **decide how to classify your data in order to select systems above**

If requested, include this information:

- **Lancaster University is NOT ISO 27001 certified, but we adhere to the principles of the standard, which is always acceptable.**

You could also describe, if appropriate:

- **Various secure tools available, e.g. Vmware**
- **Will the back up process you use be automated or manual? Data on University filestores is backed up automatically nightly.**

If your dataset is expected to be bigger than 1TB, you will probably need to let ISS know and request additional storage space using this form: ISS File Storage Request

Relevant policy managed by ISS:
Lancaster University Information Security Policy (pdf)

For more information and further help from ISS visit this page: Information Security
For more information and further help from Contracts visit this page: Contracts Team

The project's data will be stored in REDCap and on secure, electronic folders at University of York and Lancaster University (LU). Any data shared with LU or Kings College London (KCL) by the University of York during the study will be securely transferred using the University of York DropOff Service. DropOff is an internal University of York IT service. It is hosted and managed by IT Services and is powered by ZendTo, which is an open-source file transfer software. DropOff is hosted in the University's AWS environment. DropOff is not a third-party data processor and is an internal University service using open-source software. DropOff runs in the University's AWS environment in the UK, using the AWS London region: eu-west-2. Files uploaded to DropOff are retained temporarily and automatically deleted after 14 days. DropOff has been approved by the University's Cyber Risk Assessment process and has been penetration tested by third-party penetration testing partner. Lancaster University's Information Governance Manager & Data Protection Officer has approved the use of DropOff system for data transfer from York University.

Participants' contact details, consent forms, clinical outcome data and health economic data will be securely stored on York Trials Unit's (YTU) REDCap system. Copies of consent forms will be downloaded to the Trial's Teams Channel at LU (accessible only to the research team). Pseudonymised data downloaded from REDCap for monitoring and analysis purposes will be stored on secure drives at University of York. Only University of York research staff working on the study will have access to these

folders and to the study data held in REDCap both of which require SSO and 2-factor authentication. University of York servers are secured in locked cabinets in purpose-built data centres with access to buildings managed by a dedicated data centre team. Storage is replicated across multiple locations for business continuity purposes. Backups are taken daily and a copy is stored for 90 days (35 days for AWS Backup) in immutable cloud storage located in enterprise level UK data centres. Snapshots are also taken at regular intervals throughout the day. The University of York's backup policy is at

https://www.york.ac.uk/it-services/tools/backups/

The study will use private LUs Microsoft Teams Channels which have been set up specifically for this study. Only project co-applicants and members of the research team have access to the main folder. Sensitive participant information such as participant personal details (including addresses, email addresses, name, phone number), levels of deprivation, GP details, eligibility data and recordings will be stored on a Lancaster University Teams Channel 'Core Trial Team Channel' with access only to members of the research team. Personal data will be deleted one year after the end of the trial, as indicated in the consent forms. As noted on the consent form, GP details are deleted once a participant has finished their time in the trial, or if they choose to withdraw from the trial. Eligibility data and levels of deprivation data will be shared with YTU for analysis using secure links through Microsoft Teams.

Health economic data shared with KCL by the University of York through DropOff service

for analysis will be stored on KCL's maintained OneDrive for business for the duration of the study. Analysis will be carried out on KCL secure and managed PCs or laptops, which are compliant with relevant GDPR and cyber security protocols.

Data that may unblind blinded members of the research team will be stored on a separate Teams Channel, or in a locked folder on the main trial's Teams Channel with access provided only to unblinded research team members.

The feedback survey for the qualitative aspect of the study will be stored on Qualtrics, hosted on the Lancaster University server, with access only to study team members delegated to the qualitative study.

The feedback interview recordings will be securely stored on a separate Lancaster University Teams channel dedicated to the transcriptions, until they are transcribed. Access to this Teams channel will be restricted to the transcriber, and research team members with delegated responsibility for the qualitative study. The transcriber will sign a confidentiality agreement before gaining access to the Teams Channel. After transcription and review of the recordings by the qualitative researcher, the recordings will be securely deleted. The pseudonymised transcripts will then be stored in the locked folder on the trial's main Teams Channel in Microsoft Word (.docx) format. New participant IDs will be provided to participant's transcriptions so that clinical and economic data is not linked with their qualitative data. The transcripts will be uploaded and analysed on Lancaster University's NVivo software.

Access to the Trial's Teams Chanels and Qualtrics is managed by the University's Information Systems Services (ISS) and requires SSO and 2-factor authentication for access. All data will be stored on the shared Teams system or Qualtrics (where applicable), rather than on any individual team member's devices. Access to the Teams channel or Teams folder will be managed by the Trial Manager; any research team members who have completed their delegated tasks will be removed from the Teams Channel and will no longer have access to files and folders.

The intervention website is hosted in Amazon Web Services (AWS), AWS service terms are outlined here; https://aws.amazon.com/service-terms/ section 1.14 includes an AWS UK GDPR addendum. Data is encrypted with a key only held onsite, so AWS staff cannot access data. Access to the data which includes participants emails, participant numbers and group allocation requires SSO and 2-factor authentication for access. Access to the anonymised intervention usage data is controlled by Lancaster University's ISS team, and only delegated members of the research team are permitted access to this data which is username and password protected. For analysis the IBPI website usage data will be shared in .cvs format using secure Microsoft Teams links.

Ethics and Legal Compliance

For datasets that include personal data of living individuals, you will need to consider:

- **Under GDPR law, what is the Lawful Basis for Processing Data?**
- **What is the Informed Consent process you have designed? Will you share consent forms alongside the final dataset?**
- **How will you perform a Disclosure Assessment on the final dataset to check whether a living individual can be identified within it?**
- **What Anonymisation Techniques will you use on the final dataset? How will these retain the usability of the dataset?**

For all datasets, you will need to consider:

- **Is your dataset suitable for sharing? It is fine to make the decision that it is not, as long as this is fully justified within the DMP.**
- **What Access Control will you apply to the dataset? Will it be Open, Controlled Access, Embargoed or Closed? Include full justification within the DMP.**
  - **What mechanisms within your chosen data repository will be used to control access?**
  - **What criteria will you use to decide who to allow to access the dataset?**
- **What Licensing will you apply to the finalised dataset that you will share? This will usually be a Creative**

Commons license, the the default choice is CC-BY. More information at the following guides:
  - **Lancaster University - Choosing a License**
  - **Creative Commons License Chooser**
  - **Digital Curation Centre - How to License Research Data**
- **Does the dataset contain any Intellectual Property or potential commercially sensitive information? This may include issues with copyrights or patents. Further detailed support is available from the following teams:**
  - **Lancaster University - Copyright**
  - **Lancaster University - Intellectual Property**

More information and support is available from the following teams:
Lancaster University - Library
Lancaster University - Research Integrity, Ethics and Governance
Lancaster University - Information Governance, Data Protection
Lancaster University - IP and Copyright
Lancaster University - Contracts Team

The lawful basis for processing personal data is for research purposes under Article 6 (1) (e) of the GDPR: *Processing is necessary for the performance of a task carried out in the public interest.*

The Data Monitoring and Ethics Committee (DMEC) will meet twice a year to have oversight of trial data and to discuss any ethical concerns that are raised from viewing the blinded data. The DMEC will meet throughout the trial, and the research team will action advice from these meetings.

Consent

Written consent will be obtained at the point of registration, where participants consent to be contacted up until a year after the trial has ended. Participants will consent separately for the main trial. Participants consenting to be contacted for the qualitative study will be invited to a feedback survey and will be required to provide additional consent prior to completing the feedback survey. Participants who have completed the feedback survey and who agree to be contacted for the feedback interview will need to provide consent before being interviewed.

Information sheets for the main trial and feedback interview will make it clear that data obtained will be pseudonymised so that the identity of participants will remain confidential. To engage with the feedback survey and feedback interview participants are required to agree on their consent form for pseudonymised quotes to be used in publications, training events and conferences.

Participants agree in their consent forms for their webpage/website data to be viewed by the research team.

Consent forms for the full trial, feedback survey and feedback interview will be archived separately to the dataset in Lancaster University's repository. The consent forms will inform which participants have consented to their data being used for secondary analysis purposes.

Anonymisation

For the outcome survey .csv dataset, all personally identifying information such as names and email addresses is not accessible to the York Trial Unit statisticians, and as such will not be included when downloading the data from REDCap. Participant Identification Numbers will be assigned to each participant. The same Participant Identification Numbers will be used for the IBPI website usage data and for participants participating in the feedback survey. Separate Participant Identification Numbers will be used for the feedback interviews. Consent forms will not be shared alongside the final dataset but will be archived to ensure that any sharing of data for secondary analysis complies with the participants' consent.

Intellectual Property (IP)

Any IP or copyright created as part of the study will be managed through the NIHR contract with Lancaster University and its collaboration agreement with the other institutions involved in the study.

Publications from the project as well as the resulting IBPI website will be made freely available in accordance with the above contract and agreement.

Access Control

The outcome survey dataset, feedback survey dataset and the IBPI website usage dataset will be archived on Lancaster University's PURE, an open repository, and will be available to other researchers through controlled access and reasonable request, on permission from the CI (or delegated individual) and YTU statistician. Transcriptions from the feedback interviews will not be archived on PURE, however a selection of approved pseudonymised quotes will be stored and available open access. Participant data excluding personal data will be stored by participant ID until at least 10 years after the final publication to facilitate subject access requests.

Selection and Preservation

- **What data will be deleted at the end of the active research phase?**
  - **How long after the analysis is complete will you delete this? A rough average amount of time for this is from 6 months to 5 years.**
- **What data will be retained long term, either through sharing an open or controlled access dataset, or archiving a closed dataset?**

    - **Where will you store this data? This will most likely be in a data repository, but if it is very sensitive data that even repository administrators are unable to access, then departmental filestore is appropriate. Storing data long term on a web page is not recommended.**
    - **How long will you store this data for? Archiving of data should be considered as indefinite or 'forever', however, most data repositories will specify a length of time that they can guarantee the preservation of data for before it will need some work to preserve further. A rough average amount of time for this is 10 years.**
- **How will you make the decisions between what to keep and what to delete? Consider: contracts, regulations, legal issues, data subjects, ethical issues**

In line with the University of York's policies, the REDCap outcome survey data files and system files will be retained to allow, if necessary, reconstruction of the REDCap database and the data within it. At the end of the study the REDCap project will be locked and taken offline. After a suitable period (once regular access to the electronic data and records passes) the data will be exported and transferred to the YTU archiving filestore. Personal information will be removed from these data after 12 months. Pseudonymised data downloaded from REDCap for monitoring and analysis purposes will be stored on secure drives at University of York throughout the duration of the trial and subsequently transferred to the YTU archiving filestore. A copy of the final dataset used for analysis will be shared with Lancaster University at the end of the study period using DropOff which is a secure encrypted data transfer service approved by University of York. University of York and Lancaster University are joint controllers of the data and have a Data Processing Agreement in place. As per the study protocol, after the study period, the final dataset used for analysis will be archived on Lancaster's repository PURE for a minimum of 10 years. Following archiving, any data that was stored on the trial's Teams Channels will be deleted from The Teams Channel. Economic data will not be stored at KCL beyond the study period and will be securely deleted at the end of the study period.

Only selected members of the trial team will have access to this data during the study, and accounts to access the data will be set-up by the Information Systems Services (ISS) team using Amazon Web Services (AWS). The pseudonymised files will be downloaded in .csv format and will be shared with and analysed by York Trials Unit (YTU).

Consent forms will be downloaded from REDCap and will be stored on the trial's Teams Channel, accessible only to researchers working on the trial.

Participant GP details will not be stored longer than is necessary and will be securely deleted from the MS Forms saved on the trial's Teams Channel. GP details will be deleted in the event that a participant withdraws from the trial or completes their time in the study.

Participant contact details collected on MS Forms saved to the trial's Teams Channel will be stored for one year following the end of the trial. These will be securely deleted a year after the trial has ended. This is with the exception of the pseudonymised xls. dataset which includes participant postcodes and associated levels of deprivation data. This will be stored on a secure Teams channel and shared via secure Microsoft Teams link with University of York for data analysis purposes.

The eligibility interviews have been deleted at the point of eligibility confirmation for those consenting with the participant information sheet prior to v10.0. All eligibility interview recordings with participants consenting with a participant information sheet v10.0 and later will be kept until the end of the trial. When the trial ends, eligibility interview recordings will be securely deleted from the trials' Teams Channel where they are stored.

The feedback interview recordings will be deleted during the study period, after transcription and reviewing of the recordings by the qualitative researcher (to produce initial reflections) 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 pseudo-anonymised quotes will be made available on request from the CI (or delegated individual), which will also be uploaded to PURE. A selection of pseudo-anonymised quotes will also be published in the outcome papers.

All data will be retained in accordance with Lancaster and York Data Protection and Information Security policies respectively.

The data identifier would refer to the data held in Lancaster's PURE repository.

Access to the data will be on request and approval from the CI (or delegated individual) and a statistician at YTU; queries relating to health economic data will be managed by a health economist at KCL. The CI (or delegated individual) will ensure that the request is legitimate and reasonable, and the statistician's role will be to ensure that sharing the data is operationally viable, i.e. it is feasible to do within the data request. Data requests will be made via a data request form; the data request form will be jointly developed by Lancaster University (LU) and YTU as LU and YTU are joint data controllers.

Data Sharing

- **When will you share the finalised dataset?**
    - **How long will you need exclusive use of the data for before it will be shared?**
    - **This could be for the validation of results, in which case an average amount of time is 6 months to 5 years.**
    - **It could also be an embargo to allow publication, in which case an average amount of time is 12 months.**
- **How will you share the finalised dataset?**
    - **The default choice is to use a data repository, please see advice on this page: Lancaster University Depositing Your Data**

    - **You can also share the data within the paper, or state that data is available on request, but this is not normally acceptable, particularly if your research is funded.**
- **What are the details of the repository you have chosen? Is there an appraisal and acceptance procedure? Is there evidence of it being a trustworthy repository, for example, through CoreTrustSeal certification?**
- **What are the access conditions that will be applied to the dataset, i.e. Open, Controlled or Closed? How is this managed within the repository? Will a Data Sharing Agreement form part of any controlled access conditions?**
- **How will you disseminate the data?**

Lancaster University's (LU) repository PURE was chosen to keep data preserved for at least 10 years and increase its visibility.

The pseudonymised .csv outcome survey dataset (including health economic data) and relevant codebooks, indices of deprivation dataset, eligibility/diagnosis dataset, feedback survey dataset and the IBPI website usage dataset will be stored on the Lancaster University PURE repository after publication of research outputs at the end of the research, for 10 years. This will be available for research purposes under controlled access, after approval from the CI (or delegated individual) and York Trial's Unit's (YTU's) statistician.

The pseudonymised feedback interview transcripts in .docx format will be archived on the Lancaster University PURE repository but will be a closed dataset. Given the sensitive nature of the qualitative data, we will not share transcripts due to the potential for the narrative of a transcript to indirectly undermine the anonymity of the participant. However, a collection of approved pseudonymised quotes will be available for research purposes as they will be uploaded to Lancaster University's repository and will be included in publications.

The results of this research will be shared via conferences, training events, peer-reviewed open access journal articles and through our website. Bipolar UK will also support dissemination through their newsletters/website and/or through their e-community.

Responsibilities and Resources

Responsibilities: who is doing what within this DMP?
This could be just yourself, in which case that can be stated here, but you could be part of an international research team, in which case you will need to make clear who has responsibility for the following:

- **Data Management tasks**
- **Implementing the DMP**
- **reviewing and revising the DMP**

Resources: do you need anything additional to implement this DMP?
You could just be using existing departmental and institutional resources and your own time, but you could need additional resources that might include employing freelancers to undertake some aspects of the DMP, or procuring extra storage or specialist software. Consider the following:

- **Additional hardware or software**
- **Additional staffing**
- **Additional storage**
- **Repository charges**
- **Specific funder requirements**

External partners: how will you manage responsibilities externally?
Careful consideration needs to be given when working with external partners, particularly if these are international. If it is ever unclear, it would default to the Principle Investigator. Consider the following:

- **Splitting responsibilities**
- **Data ownership and IP**
- **Contracts**

The grant holder team and researchers will all be involved in the development and implementation of data collection systems and analysis. They will contribute to data management and to production and dissemination of outputs. We intend to make the intervention (website) - if found to be safe and effective - freely available. The website may be hosted by Lancaster University (LU), Lancashire and South Cumbria NHS Foundation Trust, Bipolar UK or other organisations subject to contractual agreements.

A data processing agreement is in place with York University and LU being joint data controllers.

The Data Monitoring and Ethics Committee (DMEC) will meet twice a year to have oversight of trial data management throughout the trial, and the research team will action advice from these meetings.

The research team at LU will work with LU library and PURE on ensuring data is appropriately stored and curated. The research team at York Trials Unit will work with their Data Management Team to ensure the data is archived appropriately according to

applicable guidance and advise the LU team when archiving is conducted.

Planned Research Outputs

Publication - "A randomised controlled clinical and cost effectiveness trial of an online integrated bipolar parenting intervention (IBPI) compared to treatment as usual in improving child emotional and behavioural outcomes: a study protocol"

Abstract

Background

Bipolar disorder (BD) is a severe mental health problem linked to substantial personal and social costs. Many individuals living with bipolar disorder are parents. Due to the nature of the condition, parents with BD often experience challenges in delivering consistent parenting. In addition, up to 60% of their children experience at least one mental health problem in childhood and are at increased risk of future severe mental health problems including bipolar disorder. This paper describes the rationale and protocol for a definitive randomised controlled trial of a new digital intervention (Integrated Bipolar Parenting Intervention; IBPI) to support effective parenting in the context of BD.

Methods and design

The randomised controlled clinical and cost-effectiveness trial compares IBPI plus treatment as usual (TAU) with TAU alone. Parents with BD with a child aged 4–11 years old and living in the UK will be recruited through the NHS, mental health charities, and social media. Participants will be screened to confirm a clinical diagnosis of BD. They will then complete baseline assessments and be randomised to receive either IBPI + TAU or TAU with follow up assessments after 24- and 48- weeks. The primary clinical outcome is child emotional and behaviour problems measured by the Strengths and Difficulties Questionnaire at 24 weeks. The primary economic evaluation will be a cost-utility analysis at 24-weeks with quality-adjusted life years (QALYs) measured using the Child Health Utility 9 Dimensions measure of health-related quality of life. Secondary outcomes include parental mood and confidence and family functioning at 24- and 48- weeks, and child emotional and behavioural problems and health economic outcomes at 48 weeks.

Discussion

Despite the challenges faced by children of parents with BD and the parents themselves, research on how to improve their lives is lacking. This will be the first definitive trial of a tailored intervention that aims to improve child and parent outcomes. Results will be reported in line with CONSORT guidance for clinical and health economic findings.

Publication - "CoDesign of a digital intervention for parents with bipolar disorder informed by integrated knowledge translation principles"

AbstractObjectivesTo provide detailed information on the codesign of a digital intervention to support parents with bipolar disorder (BD) who have young children. Each step of this process is reported, as well as a detailed description of the final version of the intervention in line with the TIDieR framework.MethodsClinical experience and lived experience experts participated in online workshops, meetings, and remote feedback requests, informed by Integrated Knowledge Translation (IKT) principles. The IKT research group responded to each phase of recommendations from the knowledge users.ResultsFive clinical experience experts and six lived experience experts engaged with the codesign process. Their recommendations for principles, content, look, and feel, and functionality of the digital intervention were structured over five iterative phases. This led to a final implemented design that was identified by the clinical and lived experience experts (referred to together as the knowledge users group) as genuinely reflecting their input.ConclusionsThe IKT principles offer an accessible structure for engaging with clinical and lived experience experts throughout a codesign process, in this case for a digital intervention for parents with BD. The resulting intervention is described in detail for transparency to aid further evaluation and development and to help other teams planning codesign approaches to intervention development.

Planned research output details

Title	DOI	Type	Release date	Access level	Repository(ies)	File size	License	Metadata standard(s)	May contain sensitive data?	May contain PII?
A randomised controlled clinical and cost effectiv ...	10.1186/s12888-025-07214-3 ...	Publication	2025-08-26	Open	None specified		Creative Commons Attribution 4.0 International	None specified	No	No
CoDesign of a digital intervention for parents wit ...	10.1111/bdi.13468 ...	Publication	2024-08-22	Open	None specified		Creative Commons Attribution 4.0 International	None specified	No	No