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PARTICIPANT INFORMATION SHEET

Mental Health Mission Mood Disorder cohort Study

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Introduction

We are inviting you to take part in the Mental Health Mission Mood Disorder Cohort Study. Before you decide to take part, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information and discuss it with others if you wish. Please ask the study team if there if anything that is not clear or if you would like more information.

What is the Mental Health Mission Mood Disorder Cohort Study?

The Mental Health Mission Mood Disorder Cohort Study is a study that is collecting data from a group of people (a "cohort") who have depression that has been difficult to treat. The study is funded by the National Institute for Health and Care Research (NIHR; the research arm of the NHS) and the Office for Life Science.

What is the purpose of the study?

We want to increase our understanding about depression. Overall, we aim to improve the lives of people experiencing depression, by:

- Giving people with depression the best opportunity to take part in research studies
- Giving researchers controlled access to research data from a large number of people so they can ask questions such as why some people respond to treatments and others don't
- Helping to develop more effective treatment approaches

Why have I been invited?

The study will involve initially up to 2,000 patients aged 18 years and over with major depressive disorder or bipolar disorder who receive a clinical assessment within a mood disorder research clinic that is part of the UK Mental Health Mission Mood Disorder Network.

Do I have to take part?

No, participation is entirely voluntary, and you can withdraw from the study without giving a reason if you later change your mind.

If you decide not to take part, or decide to withdraw from the study, it will not affect your medical care in any way.

What does taking part involve?

Everyone who attends the CaPE clinic receives a clinical assessment from a doctor specialising in the treatment of depression. This is part of routine clinical care (not the study). The outcomes from these assessments are shared with your GP to help decide any future treatment options.

In addition, you can choose to join the Mental Health Mission Mood Disorder Cohort Study, which is this study. There are several options, and you decide how you want to take part:

Storage of clinical assessment details and questionnaire responses in the study database

- With your permission, medical notes from the clinical assessment you complete at the CaPE clinic will be added to the study database. You will not have any extra assessments with your clinician.
- You will be asked to complete a set of questionnaires about your demographic information, mental health, emotional wellbeing and quality of life (although useful for routine care, these are being collected as part of the study).

- This information will be stored without your name or other information that could be used to identify you.

Completion of additional, optional research activities

You will also be invited to participate in optional additional research activities. These activities are for research purposes only and will not affect the clinical care you receive within the clinic. These activities may include:

1. **Online tasks:** You can complete online tasks that test your learning and thinking skills, taking approximately 20 minutes
2. **Biosample:** You will be asked if you would like to provide a blood sample of up to 100ml (approximately 7 tablespoons), in some cases, following agreement with the research team, a saliva sample may be provided instead. This sample collection will be performed by a member of the research team with the correct training. It this biosample fails (for example, if it is not enough or it clots), we will contact you for a second visit; you are free to choose not to provide a second biosample.
3. **Follow-up questionnaires:** You can complete a smaller number of questionnaires every three months, taking approximately 25 minutes each time for the duration of the study (a maximum of up to 3 years). You may decide to stop completing these questionnaires at any time. Completion of questionnaires will be via electronic means or by contact with a member of the study team.
4. **Joining the GLAD study:** When you attend the clinic, we will also invite you to join the Genetic Links to Anxiety and Depression (GLAD) Study. This study takes place online and involves completing a 30-60 minute questionnaire to better understand your experiences of depression. The GLAD study has a separate consent form and information sheet explaining the study. If you agree to this, the data you provide in our study (including questionnaire data and task data) will be securely transferred to the GLAD study. This data will not include information that directly identifies you, rather it will include a study ID number that will allow your data to be linked with that you have provided to GLAD.
5. **Linking my study data to other databases:** You will be asked if you agree to "link" your study data to other datasets that are routinely collected. An example of this would be linking with your GP or secondary care medical records. In this case, we would not transfer your study data to other datasets, rather we would analyse data held about you in other existing datasets. In order to make sure we have linked to the correct peoples' data in these datasets, we would securely transfer the following personally identifying data to them: NHS Number, full name, date of birth, sex, postcode. This information is only used to match your records. Once the records are linked the personally identifiers are removed and replaced with a study ID number.

The data collected from these research activities will be stored in the study database along with data from your clinical assessment, without your personal details.

Hearing about future research studies

You can choose to receive information about future research studies into depression. If you agree to this, you will be invited to participate in other studies based on data held, accessed or analysed about you (including data of any samples you have consented to donate).

If you agree to hear about future research studies, all contact will come from the research team of this study in the first instance via your preferred contact method. The study team will provide information about the study and contact details of the relevant research team if you want to contact them for further information.

Agreeing to be contacted about future research does not mean you have to take part in any future study. The researchers will give you full information about their study, let you ask questions and ask you to complete a separate consent form.

Your contact details would be held securely in a contact database, on password protected computers in the Department of Psychiatry, accessible only by authorised individuals. You can request for your details to be removed from this database at any time if you wish.

How will we use information about you?

We need to collect information from you for this research project, and we will obtain your informed consent for this. This information will include, but not be limited to, your name, NHS number, date of birth, contact details and medical history. We will use this information to do the research or to check your records to make sure that the research is being done properly. We will also take a biosample if you consent to doing so (optional):

Your sample will be used for several types of research, including:

- Looking at your DNA to study specific genes we're interested in
- Studying how your genes turn on and off by examining your RNA
- Testing for other biological markers and proteins in your body
- Making a renewable source of your cells that scientists can grow in the lab for future research. This means they can study your cells without needing to collect more samples from you.

The information you provide as part of the study visit and follow-up questions, along with your medical notes, will be stored as part of the Mental Health Mission Mood Disorder Cohort Study, in a secure data environment, provided by the sponsor (University of Oxford). If you choose to participate in the GLAD study as well, the questionnaire data and the biological data you provide will be shared and linked with the GLAD Study team at King's College London to improve our understanding of depression. The GLAD study is part of the NIHR BioResource and the data you provide will also be shared with NIHR BioResource.
We will keep all information about you safe and secure. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. This is known as being pseudonymised. Approved members of our research team will need to keep a key with your code so that we can link your data with you and get in touch with you in the future. We will write our reports in a way that no-one can work out that you took part in the study.

To make best use of resources we will share pseudonymised data with other researchers other than the study team for future research studies, where this research has been ethically approved. This will include sharing your data with the following types of individuals/organisations: individuals working in the UK or abroad, universities and commercial companies in the UK and abroad. It will not be possible for you to be personally identified by the data shared.

You will have the option to give additional permission for us to:

- Provide your samples and associated data to an ethically approved Biobank when it is no longer needed in this study. This will ensure that all the data that you have kindly provided for research does not get destroyed in the future and is kept for future researchers to look at.
- Link to other sources, including, but not limited to, health, social, and education database(s). This will help complement the information you provide as part of this study and give us a way to better enable the research to improve patient lives.

Will I get information about my biological samples and clinical data results?

Only the results and outcomes from your clinical assessment will be shared with your doctor to help decide any future treatment options.
The data collected from questionnaires, online tasks and blood samples are for research only and have not been validated for diagnosis or medical care so will not be given to your GP or treating clinical team. Additionally, the data from samples may not be analysed quickly and could be tested months or years after sample collection.

What should I consider?

By taking part, you can still continue to take your regular medication and other prescribed or over-the-counter medicines. You can also participate if you are involved in other research studies.

Are there any possible disadvantages or risks from taking part?

This study does not include any treatment changes or invasive techniques apart from taking blood. Some people will feel mild discomfort when giving a blood sample; mild bruising may occur.

As part of the study, you will be asked questions about symptoms of depression that might be upsetting (for example, feeling suicidal). If you would do not want to answer these questions it would be best not to enrol in the study.

If the study team, during the clinical assessment visit, become aware of important risk-related information, this will be passed on to your clinical team. However, responses to questionnaires will not be routinely monitored and therefore no timely action will be taken based on these results. Details of urgent and emergency care services will be provided along with the questionnaires and you remain responsible for seeking support from your healthcare team if needed.

What are the possible benefits of taking part?

We hope that the information that you provide will help us to develop more effective approaches to clinical care and treatments, and to improve longer-term care for people with depression or bipolar disorder.

The outcome of the clinical assessment will be shared with your GP. By completing questionnaire data via online methods, you will be able to see displays of your questionnaire responses over time and this may be helpful for you. If you wish, you can share these with your clinician.

What will happen if I do not want to continue taking part?

You are free to withdraw from the study at any time, without giving reason. Your usual medical care will not be affected in any way if you decide not to continue. The study team also have the right to withdraw someone from the study.

If you decide to withdraw, you will have two different options for doing so:

- **No further contact**
  You will be asked whether you give your permission for us to retain and use the data/samples that you have provided before your decision to stop taking part, but we will no longer contact you with any follow-up questionnaires and/or invite you take part in other research.
- **No further use**
  You will also have the option to request to fully withdraw, and by doing so, the research data and samples that you have provided will be destroyed.

If you do not specify whether you would like to withdraw under 'no further contact' or 'no further use', we will assume the former and simply not contact you again for this or future studies; however, we will not destroy samples and data.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. It is not possible to remove your pseudonymised data from research datasets which have already been published or shared, or to delete your data from any associated linked datasets which we have not collected as part of this study.

Your personal information will be retained in an archive so that a record remains of your initial consent and the withdrawal process. In the unlikely event that you lose capacity to make decisions about the research database, the research team will retain your identifiable sample and data and continue to use it in research.

To withdraw, please email the study team on Rebecca.Woodhouse@cntw.nhs.uk

Will my taking part in the study be kept confidential?

Yes, all study records and samples will be identified only by a code. We will only use your name, contact information and NHS number where this is necessary to contact you and to link to your data from research activities. Information that can identify you will be held securely and separately from research activity data in a separate database accessible by authorised individuals. Details of your clinical assessment will be stored on your health records and a summary of the assessment will be sent to your GP. Your GP will be informed if any issues of concern arise in the assessment.

Responsible members of the University of Oxford, regulatory authorities and Cumbria, Northumberland, Tyne and Wear NHS may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Your data will be stored by the University of Oxford, King's College London, and the NIHR BioResource for use in current and future ethically approved research aimed at better understanding the development and treatment of a range of health conditions. Questionnaire and cognitive assessment data will be stored on computer servers managed or contracted by the University of Oxford, King's College London and the NIHR BioResource, in password-protected databases.

Questionnaires will be filled out using an online system called "true colours" which is managed by the Oxford Health NHS Trust and the company AVCO. The data from these questionnaires will be stored on the UK based secure servers of Amazon Web Services before being securely transferred to the study database. If you complete online tasks, the data from these tasks (which will be anonymous) will be stored on the servers of the company Cauldron Science Ltd within the European Union, before being downloaded into the study database.

How your data will be used:

- We need to collect information from you and your clinical assessment records to carry out this study
- We will use the minimum amount of personal information necessary to protect your privacy
- Some of your data will be shared with the study team at other universities and other organisations working on mood disorder research to combine analysis of a large number of people. It will not be possible to identify you personally from the data

that is shared, but your data can be linked back to you by the study team using the unique ID number.

- Anonymised data may be shared for use in ethically approved research projects, which may take place in hospitals, universities, non-profit institutions or commercial laboratories worldwide (see below for more details).

How long your data will be kept:

- Any personal information related to the study, such as consent forms, will be stored securely at the University of Oxford for 10 years after the study ends. This is part of the research record.
- If you agree to let your samples be used in future research, your consent form will be kept securely until the samples are no longer needed
- If you agree to be contacted for future research, we will keep your consent form until your details are removed from our database. Your consent form and personal details will be stored separately from your research data

For financial purposes:

- If you provide bank details for reimbursement of travel expenses, these will be kept for 7 years, inline with the University of Oxford's financial policy

Will I be reimbursed for taking part?

Where travel to a research clinic is required to participate in any research activities (not including the clinical assessment which people receive whether they choose to participate in this study or not), reasonable travel expenses will be paid to you.

What will happen to my data?

Data protection legislation requires that we, the University of Oxford (whose legal name is The Chancellor Masters and Scholars of the University of Oxford), state the legal basis for processing information about you. In the case of research, this is a 'task in the public interest'. The University of Oxford is the sponsor for this study and is responsible for looking after your information and using it properly.

We will need to use information from your study visits, including medical records and personal information for this research project. We will share your information related to this research project with the following types of organisations: academic and healthcare organisations involved in the research.

This information will include your NHS number, name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure by:

- storing it on encrypted, password protected servers,
- or in locked filing cabinets (where pen and paper forms are used).
- Assigning you a unique study ID to pseudoanonymise your data.
- Storing any identifiable information (e.g., name, NHS number) in a separate, password-protected file from your research data.

- Keeping electronic data on secure, encrypted University of Oxford servers with access restricted to authorised study team members.
- Storing consent forms in locked filing cabinets in swipe-access only research offices.
- Limiting access to your personal information to only those who need it for research or regulatory oversight purposes. Where data is to be transferred to other researchers, this will only occur where the external research team have ethical approval for their analysis and where a contract is in place with the external institution which protects your personal data.

International Transfers

We may share data about you outside the UK for research related purposes to: further analyse the data.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it may be with the following sorts of organisations: commercial and non-commercial organisations (e.g. Universities).

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- (some of) the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data indefinitely and personally identifying data for 10 years after the end of the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records. If you do not want this to happen, tell us and we will stop.

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK, by:

- asking one of the research team- Rebecca.woodhouse@cntw.nhs.uk
- sending an email to Rebecca.woodhouse@cntw.nhs.uk
- calling us on 0191 2468647
- contacting the University's Data Protection Officer data.protection@admin.ox.ac.uk
- looking at the University's privacy notice available at: How we use your personal data for research purposes | Compliance.

If you would like to find out more about the use of confidential data in research, the HRA has developed a general information leaflet which is available at: Patient data and research leaflet - Health Research Authority.

We may use third party service providers or subcontractors to help with some of the research activities we carry out (e.g. IT provision, survey provision, transcription services etc.). We may therefore share your personal data with these providers when it is necessary to do so to allow them to carry out the services we require them to provide. However, we require all our third-party providers to have appropriate security measures in place to protect your data and we only allow them to process your data for the specific purposes we have stated in our instructions.

What will happen to the results of this study?

Results from research will be published in scientific journals and presented at national and international conferences. However, only general conclusions from large groups of participants will be presented, and it will not be possible to identify individuals.

What if there is a problem?

If you have a concern about any aspect of this study, please speak with the study team. They will do their best to answer your questions.

The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary.

NHS indemnity operates in respect of the clinical treatment provided.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, contact Professor Michael Browning (Michael.browning@psych.ox.ac.uk) or you may contact University of Oxford Research Governance, Ethics & Assurance (RGEA) at rgea.complaints@admin.ox.ac.uk

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.

If you wish to contact the PALS team please contact:

PALS for North Cumbria and North of Tyne: Email: pals@nhct.nhs.uk Tel: 0800 032 0202

PALS for Sunderland, Gateshead and South of Tyneside: Email: pals@cntw.nhs.uk Tel 0800 328 4397

How have patients and the public been involved in this study?

We value the input of patients and the public in shaping our research to ensure it is relevant, respectful and understandable. For this study, we have worked closely with people with lived experience of mood disorders throughout the design process, selection of questionnaires and reviewing study materials to ensure information provided is clear, easy to understand and covers all important aspects of the study.

Who is organising and funding the study?

The University of Oxford is sponsoring the study. The Chief Investigator is Professor Michael Browning. The study is funded by the National Institute for Health and Care Research (NIHR) Mental Health Translational Research Collaboration (MH-TRC) Mental Health Mission.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by Surrey Borders Research Ethics Committee.

Further information and contact details:

Please contact CaPE Clinic: Email: CaPE@cntw.nhs.uk , Landline: 0191 245 6845,
Mobile: 07919 881400

Rebecca Woodhouse by email: Rebecca.woodhouse@cntw.nhs.uk,
or phone: 0191 2468647

Thank you for considering your involvement in this study and taking the time to read this information sheet.