

Co-developing a research agenda for PMDD in the UK

PARTICIPANT INFORMATION SHEET PMDD FOCUS GROUP

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Why have I been invited to take part?

You are invited to take part in a discussion with other people because you have insight of either living with, managing or supporting someone with Premenstrual Dysphoric Disorder (PMDD).

Taking part in the discussion (focus group) is entirely up to you. Before you decide, we would like you to understand why this project is being done and what it will involve for you.

This Participant Information Sheet tells you the purpose of the project, what will happen to you if you take part and detailed information about the conduct of the project. Please take the opportunity to ask any questions you have and to ask for more information if anything is unclear.

What is the purpose of the study?

This project aims to create a PMDD research agenda (i.e. a plan for future PMDD research). The research agenda will be developed using insight and experience from a range of people.

These include: (i) people living with PMDD; (ii) health care professionals who see patients with PMDD; (iii) organisations who support people living with PMDD; (iv) people who are involved in emergency mental health crisis support; and (v) researchers involved in suicide prevention. By bringing together insight from all of these people we hope to create a research agenda which makes a difference to PMDD management in the UK.

What would taking part involve?

You will be invited to take part in a one-off discussion with 5, 6 or 7 other people (known as a focus group). The people in your focus group will be in a similar category to you e.g. if you are someone who lives with PMDD you will be in a focus group with other people with PMDD; if you are a health care professional you will be in a focus group with other health professionals etc.

Before officially being included in a focus group you will be asked to respond to several ‘sampling’ questions. This helps us choose a range of people to include in the interview. For example, it is important that the people we speak to are not all the same, e.g. not all GPs, not all recently diagnosed etc. We will ask the following questions: (i) for people with PMDD – their ethnicity, duration and severity of PMDD etc; (ii) for health care professionals – their clinical speciality, ethnicity, years treating PMDD; (iii) for organisations – their years active in supporting people with PMDD; (iv) for emergency mental health – their area of expertise; and (v) for researchers – no sampling required. This may mean that some people will not be officially invited to the focus group, which may be disappointing for them. We do, however, appreciate your interest. The discussion will take place via Zoom on a day/time that has been mutually agreed with all people. This will be approximately 90mins long, with a comfort break included (although the focus group may run on slightly longer ,e.g. 15mins, if discussion is going well).

The researcher, Lynsay Matthews, will guide the discussion, with a focus on several different areas: (1) your personal or professional experience of PMDD; (2) your thoughts on the PMDD research has been done already; (3) your wants and needs for future PMDD research; and (4) your thoughts on what suicide prevention issues need to be considered for PMDD.

There will be opportunity to share your thoughts with the group, and also an opportunity to fill in an online scoring form where you can rank example research ideas with points. Throughout the interview, the researcher will check that you are comfortable and happy with the discussion.

The discussion will be both video and audio recorded. This will be shared with no one apart from the approved transcriber, who will use the video and audio recording to type up notes from the discussion. Once the notes have been typed up, the video recording will be deleted. The audio recording will be kept until the end of the study, stored securely in a password protected server.

The transcriber has a signed confidentiality agreement with the University of Birmingham and adheres to the General Data Protection Regulations 2018.

All participants in the focus group will receive £100 in thank you vouchers for their contribution.

What are the possible benefits of taking part?

We hope that you will benefit personally from taking part in this project by hearing other people’s insight on PMDD experiences. The knowledge gained thanks to your help, will inform a research agenda for the UK which will in turn inform future studies and treatment.

This might lead to improved management options for people with PMDD, improved guidelines for health care professionals, and improved support toolkits for organisations which support people with PMDD.

What are the possible disadvantages and risks of taking part?

There are no physical risks involved in taking part in this project. Although all discussion points will be considered carefully by the researcher, it is possible that some questions may be of a sensitive nature to some participants e.g. if they choose to share a particular experience from supporting or

managing PMDD.

The researcher will help everyone navigate these issues by highlighting if a particular discussion point may be sensitive. If you become upset the researcher will pause the discussion to check that you are okay to continue, or if you would like to have a 'breather' outside of the Zoom call.

You can also end your involvement in the discussion at any time. If you feel that you need further support, the researcher will have the contact details of relevant people and agencies that can help you. These include the peer support providers from the International Association of Premenstrual Disorders (IAPMD) (iapmd.org), the IAPMD Facebook support group (facebook.com/iapmd), and a reminder that your GP can be a first port of call for further support.

What if I do not want to take part, or decide later to withdraw?

Participation in the discussion is entirely voluntary. If you do not wish to take part, you will not have to give a reason and your decision will not affect the care you will receive. Similarly, if you do decide to take part, you will be able to withdraw from the study within five days of the focus group without giving a reason (although it helps us if you share why you changed your mind).

Please contact us using the contact details on the front of this information sheet if you would like to withdraw. If you ask to withdraw from the project more than five days after the focus group then we will keep the information about you that we have already collected.

Who has reviewed and organised the study?

This study has been funded by both the Quality Research fund of Research England and the Impact Accelerator Fund of the Economic and Social Research Council. It is organised, managed, and coordinated by Dr Lynsay Matthews at the University of Birmingham. All data will be collected and securely stored by this institution. The study has also been approved by the Science, Technology, Engineering and Mathematics Ethical Review Committee, University of Birmingham.

Will my taking part in this study be kept confidential?

All the information collected as part of this project will be handled strictly in accordance with your consent, the Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR). Very occasionally, discussions bring to light information about a participant that could affect their welfare or the welfare of others. If this happens during your focus group then the researcher may need to break confidentiality and disclose this information to the relevant authority/agency.

Certain welfare concerns may override concerns about confidentiality.

What will happen to any data I give?

The University of Birmingham will record your name and contact details to contact you about the project and to oversee the quality of the study. The only people in the University of Birmingham

who will have access to information that identifies you will be people who need to contact you, for example, to invite you to participate in the project or to audit the data collection process.

The video/audio-recording of the interview will be used to produce a typed record of the discussion, known as a transcript. This transcription may be done by a UK based specialist transcription company who will sign an agreement to keep your data confidential and stored securely. They will only have access to the recording and will have no further information about you. We will analyse the anonymised transcripts as part of our project.

Dr Lynsay Matthews is the lead researcher for this study. Dr Matthews will be using information from you in order to undertake this project and will act as the data controller for this study. This means that Dr Matthews is responsible for looking after your information and using it properly. Dr Matthews will keep identifiable information about you until the main results of the project have been published, after this time, identifiable information will be safely destroyed. Anonymised data will be stored securely **for at least 10 years after the end of the project**. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw more than 5 days after your focus group, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information by contacting Dr Lynsay Matthews (l.matthews.1@bham.ac.uk).

How will the data be anonymised?

The transcript will be checked carefully for anything that might identify you (e.g. your name, the hospital where you work or receive) and these details will be removed. Each participant will be given a unique focus group number and we will only use this to identify quotes in project reports and publications.

What will happen to the results of the project?

The findings will be used to create a research agenda for PMDD in the UK. When this agenda is ready we will inform you of the findings by email. The agenda will then be used to promote future PMDD research pathways, this may include publishing the agenda in a relevant journal, sharing it at conferences or webinars, or other formats.

What if something goes wrong?

If you are not satisfied with any aspect of the way in which you have been approached or treated during the course of the project, then please speak first to the researcher (contact details are on the front page of this information leaflet).

If you are still unhappy and wish to complain formally, you can do this through University of Birmingham complaints procedure.

Do you have any further questions?

Thank you for taking the time to read this information. If you have any questions then please feel free to get in touch with us using the contact details on the front of this leaflet.

Thank you for considering this project. Remember you can ask Lynsay any questions by emailing l.matthews.1@bham.ac.uk