Phase 2 of the study

Informed consent document

Perinatal mental health in India: a validation and cohort study

Lay title: The impact of pregnancy, childbirth and early parenting on women's mental health: understanding prevalence and women's needs

OxTREC Reference 10-20 | NIMHANS IEC (BEH.SC.DIV.)/2021 | Dr Rajendra Prasad Government Medical College IEC/48/2020 | India Health Ministry's Screening Committee Reference [approved 12/01/2022]

Type of participant: Non-perinatal (**not** currently pregnant and **not** given birth within last 12 months)

Section 1: Participant Information Sheet

Introduction

We would like to invite you to take part in our research study. To help you decide, we would like to explain why the research is being done and what it would involve for you. Please take your time in looking at this information sheet. You may like to discuss it with family members, friends or others in your community. If anything is not clear or you would like more information, please ask a study team member.

What is the purpose of the study?

Having a baby is generally thought to be a happy time. However, some women may find pregnancy, childbirth and new parenting difficult. Sometimes pregnant women or new mothers feel stress, anxiety and unhappiness. We are interested in mental health problems that are common in pregnancy and after having a baby. These include:

- depression (feeling very sad for long periods of time);
- anxiety, panic and phobias (feeling very nervous, tense or afraid);
- post-traumatic stress disorder (PTSD; feeling nervous and having flashbacks after a bad experience);
- suicidal thoughts (thoughts about life not being worth living; wishing to end one's own life);
- somatisation (long-term physical symptoms such as pain or tiredness).

If women experiencing these feelings are identified early, they can be offered support and treatment for their conditions. This study will help us to understand how many women experience these conditions, which women are most likely to experience them, and how we can identify these women as early as possible, so that we can offer help.

Why am I being invited?

We are looking for women aged 18–45 years who are pregnant or recently had a baby. We are also looking for women aged 18–45 years who are **not** pregnant and have **not** recently had a baby. By including both of these groups of women, we will be able to compare how common mental health problems are in each group. You are invited to take part in the study because you fit into the 'non-perinatal' group (**not** currently pregnant and have **not** given birth in the last 12 months).

Do I have to take part?
No, you do not have to take part in this study. Taking part is your choice. If you choose to take part, you can still change your mind and leave the study at any time, and you do not have to tell us the reason for leaving. Whether you take part or not will not affect your care now or in the future. You can take time to discuss with your family, friends, other members of your community and healthcare staff before deciding whether you want to take part.

What will happen if I decide to take part in this study?
Phase 2a: Validation Study: Cognitive Interviews
If you choose to take part, we will first ask for some information about yourself including your age, social group, socio-economic status, religion and education level. Next, we will ask you to answer some mental health questionnaires. The questionnaires will include questions on symptoms of depression (sadness), anxiety (nervousness), stress, panic, PTSD (flashbacks to bad experiences in the past), suicidal thoughts and physical symptoms. You may choose to fill in the questionnaires yourself or a research nurse can help you. After finishing the questionnaires, we will ask what thought about each question, for example whether the wording was clear and how you interpreted the question. The visit will be at your Anganwadi centre, another common place in your locality or in your home. The discussion will take place in a private space. The visit will take about 2 hours. After this there will be no more visits.

Phase 2b: Validation Study: Main Validation Study
If you choose to take part, we will first ask for some information about yourself including your age, social group, socio-economic status, religion and education level. Next, we will ask you to answer some mental health questionnaires. The questionnaires will include questions about symptoms that may be related to depression, anxiety, panic, phobias, PTSD, suicidal thoughts and physical symptoms. You may choose to fill in the questionnaires yourself or the research staff can help you. After finishing the questionnaires, a doctor will talk to you to check whether you may be experiencing any of these mental health conditions. The visit will be at your Anganwadi centre, another common place in your locality or in your home. The discussion will take place in a private space. The visit will take about 2 hours. After this there will be no more visits.

If the doctor thinks you may have a mental health problem, we will discuss our findings with you. We may ask you to see a mental health specialist worker who will offer you support and treatment. We will ask your permission before sharing your information with mental health specialists. However, in some cases, if we feel that you are extremely unwell or in danger of hurting yourself or others, we may share your details with mental health specialists even if you would prefer us not to. This is because we care about your well-being and safety, and we will act in what we believe are your best interests.

What will my information be used for?
Phase 2a: Validation Study: Focused Interview
We will use the information to check whether the questionnaires are clear and easy to understand. The interviews will help us to make changes to the wording, if necessary. Once we have versions of the questionnaires that are clear and easy to use, we will test them in the next step of the study.

Phase 2b: Validation Study: Main Validation Study

We will use the information to test how well the questionnaires work in your community. We will compare answers on the questionnaires with the results of the interview with the study doctor. This will help to us understand what score on the questionnaire is a 'high' score in your community.

Will I benefit from this study?

There will be no direct benefits to you. But, If you take part, you will help us to understand experiences of mental health problems among women in your community. This information will help us to identify these women early and offer support and treatment. In the future, we hope that the results of this study will benefit all women and their families living in your community. If you have a mental health problem then this may be picked up during the study. In this case, you may benefit from having support and treatment from the mental health specialists. Without taking part in the study, it is possible that such conditions would not be identified. During the interview, you will have a chance to talk about your mental health. Some women find it helpful to talk about how they are feeling and feel better after sharing their feelings, and this is another possible benefit of taking part.

What are the possible risks of taking part in this study?

You may find it difficult to talk about your own mental health. You may find the questions upsetting, or the questions may remind you of difficult experiences or sad times in your life. If you become distressed, we are there to help you. Our research staff will talk to you in a supportive and sensitive manner. They can help you to find more help if you need it. If you wish to stop the interview, you can do so at any time. The time taken by the study visits may be an inconvenience because you may not be able to work or take care of your other duties during this time. We will try to take as little of your time as possible. We will offer to do study visits when you are already at the Anganwadi Centre (for example, during your routine antenatal appointments) or come to your house, so that you can avoid doing extra travel.

How will my confidentiality be protected?

If you agree to take part in the study, all discussions will take place in privacy. Some personal information about you including your name, date of birth, address and telephone number will be collected. The information will be entered into an electronic (computer) form. This information will be saved safely on an internet platform (cloud-based server) hosted in India. We will do everything we can to keep your information confidential. We will use codes (encryption), keep your personal information separate from non-personal information, and use passwords to lock computer files. It will not be possible to identify you from any of the presentations or reports (publications) from the study.

How will my personal information be processed?

The processing of your personal information collected during the study is based on the need for the University doing its public interest tasks of research and teaching. We may also process your personal information if necessary for legal claims, to protect our rights, your rights and the rights of others, to meet legal obligations or to protect your interests or the interests of another person.

Will my personal information be shared with others?

Your personal information including your name, date of birth, address and telephone number will be seen only by study team members from the University of Oxford, the National Institute of Mental Health and Neurosciences (NIMHANS), Bangalore, India; Dr Rajendra Prasad Government Medical College (DRPGMC), Kangra at Tanda, Himachal Pradesh, India. We may also allow certain members of these institutions to see your information for checking (monitoring or auditing) the study. We will not make

your personal information public. We may share information from the study with companies or organisations (third parties) doing similar research. Your name and other information that could directly identify you will always be taken out before sharing. Our reason for sharing information is to get support from those organisations that lets us do our own research, such as this study. These organisations will use the information for their own interests, such as research in the field of maternal health. We will share information securely, and the organisations will be asked to treat the information following the law. We may also share your personal information when it is necessary to protect your interest or the interests of another person. For example, if we believe you are at serious risk of hurting yourself or others, we will share this information with medical staff in order to act in the best health interest of yourself or others.

What happens with the data collected / results / my samples?
We will do everything we can to make sure your information is kept confidential. We will use codes instead of your name whenever possible, separate personal information from non-personal research information, and protect computer files with passwords. The information may be shared in the future with other researchers in India and the UK to conduct further research. In these cases we will take out any information that could identify you. We will keep your personal information for as long as necessary for the purpose of the study, and to meet any legal or reporting requirements. However, we will permanently remove information which can directly identify you, such as your name, date of birth and address, from our records 18 months after the end of the study. Therefore, after 18 months, the data we hold will be anonymised and nobody will be able to identify who the data belongs to.

What is the policy on data protection?
The University of Oxford with NIMHANS will process your personal data for the research outlined above by following the ICMR guidelines. Research is a task that is done in the public interest. If you would like further information about your rights regarding your personal information please see http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/.

International sharing (transfer) of personal information
The information from the study may be shared with other researchers in India, in the UK and in other countries for further research. In these cases, we will share the information in a safe way using methods approved by the European Commission.

What are my rights with respect to my personal information?
Under some conditions, by law you have the right to:

- See your personal information that we have collected
- Ask us to correct and complete any information about you that is not correct
- Ask us to delete your personal information
- Stop the use of your personal information where we are relying on our legitimate interests
- Request us to stop using (processing) your personal information
- Ask for your personal information to be shared with another party

Depending on the circumstances and nature of your request, we may not be able to do what you have asked, for example if we think that removing your information would harm the research or we need to use your information to do a task that is in the public interest. For example, this may be the case if we feel you are at serious risk of hurting yourself or others. If you want to do any of the things listed above or if you are not happy with the way we have used your personal information, you should contact the

Principal Investigator of the site, Dr. M. Thomas Kishore: thomas@nimhans.ac.in / Professor Ashok Verma: dr.ashok_verma@yahoo.com and copying the email to the University of Oxford Information Compliance Team: data.protection@admin.ox.ac.uk. If you are still not happy, you can make a complaint with the ICO at https://ico.org.uk/concerns/. The University of Oxford's legal name is The Chancellor, Masters and Scholars of the University of Oxford.

What if I don't want to participate in this study, or I want to withdraw later?
Your taking part is voluntary and you may change your mind at any time. Leaving the study will not affect the care you receive. If you decide to leave the study at a later point, we will stop processing (using) your personal information as soon as we can. Please note that if you leave the study, we may keep and use the information collected up until the point that you left the study.

What happens at the end of the study?
To thank you for your time and for taking part in the study, we will offer you a small payment (INR 200) for the time you gave us and your travel.

Who is organising the study?
The study is being done by the National Institute of Mental Health and Neurosciences, Bangalore, India; Dr Rajendra Prasad Government Medical College Kangra at Tanda, Himachal Pradesh, India; and the University of Oxford, United Kingdom. The study is paid for by the Nuffield Department of Population Health, University of Oxford, United Kingdom.

Who has reviewed this study?
This study was reviewed and approved by the NIMHANS Institute Ethics Clearance, the Dr Rajendra Prasad Government Medical College Institutional Ethics Committee and the India Health Ministry's Screening Committee. The original protocol of the studay has been approved by the Oxford Tropical Research Ethics Committee (OxTREC), University of Oxford, UK.

What can I do if there is a problem?
The University of Oxford, as sponsor of the study, has insurance if you suffer any harm due to taking part in this study. If you would like to complain about any part of the study or about how you have been treated or approached, please contact the study team. You can speak directly to the study team at one of your visits, or contact the site principal investigator by telephone or email.

- NIMHANS: Dr M. Thomas Kishore, 080-2699-5196, thomas@nimhans.ac.in or the Chair of the hospital's ethics committee [Dean, Behavioural Sciences, NIMHANS, Bangalore 560029, telephone 080-2699-5004, deanbs@nimhans.ac.in].
- DRPGMC: Professor Ashok Verma, dr.ashok_verma@yahoo.com

You can also contact the chief investigator at the University of Oxford, United Kingdom [Dr Gracia Fellmeth, gracia.fellmeth@ndph.ox.ac.uk].

Whom should I contact for more information?
If you would like more information about the study, or if you have questions for the study team, please contact the site principal investigator:

- NIMHANS: Dr M. Thomas Kishore, thomas@nimhans.ac.in; Tel. 91-080-2699-5196 (0)
- DRPGMC: Professor Ashok Verma, dr.ashok_verma@yahoo.com

Section 2: Undertaking by the investigator

Your consent to participate in the above study is sought. You have the right to refuse consent or withdraw the same during any part of the study without giving any reason. In such an event, you will still receive best possible alternative treatment, without any prejudice. If you have any doubts about the study, please feel free to clarify the same. Even during the study, you are free to contact any of the investigators for clarification if you so desire:

- At NIMHANS: Professor Prabha Chandra, Professor Harish Thippeswamy, Professor Geeta Desai, Department of Psychiatry, NIMHANS; 080-2699 5250
- At DRPGMC: Professor (Major) Sukhjit Singh, Dr Pankaj Kanwar, Department of Psychiatry, DRPGMC

All the information/data collected from you (participant) will be kept in strict confidence.

(Dr M. Thomas Kishore)
Site principal investigator (NIMHANS)

(Professor Ashok Verma)
Site principal investigator (DRPGMC)

Section 3: Certificate of Consent

I have read and understand the information sheet [dated 21/05/2021] for this study, or someone has read and explained the information to me. I have had a chance to think about the information and ask questions. My questions have been answered clearly.

I understand that taking part is my choice. I understand that I can change my mind and leave the study at any time and I do not need to give a reason for leaving.

I understand that my rights will not change if I take part in this study or not. The care that I receive now and in the future will not be affected by whether or not I take part in this study.

I understand that this study requires one single visit. The total duration of the visit will be approximately 2 hours.

I understand that the information about me that is collected for this study will be encrypted, stored securely and used in the way we have described in the information sheet. This includes information such as my name, date of birth, address and telephone number.

I understand that the information collected in this study may be shared with study team members, healthcare workers, database managers and researchers from the University of Oxford, National Institute for Mental Health and Neurosciences (NIMHANS) and Dr Rajendra Prasad Government Medical College who are working on the study. I allow these persons to see my information.

I understand that this research will be published in a specialist academic journal and shared with other researchers and my local community. I understand that the results will not have any information that allows anyone to identify me.

I understand that if I am found to have a mental health problem, I will be offered support, treatment and follow-up from a mental health specialist. In some cases, if the study doctor feels that I am at risk of harming myself or others, the study team may share my details with mental health specialists even if I do not want this to happen.

I understand that this project has been reviewed and approved by the University of Oxford Tropical Research Ethics Committee, the Indian Health Ministry's Screening Committee, the National Institute of Mental Health and Neurosciences (NIMHANS) institutional ethics committee and the Dr. Rajendra Prasad Government Medical College institutional ethics committee.

I agree to take part in this study.

I, ……, the undersigned, voluntarily give my consent to be a participant of this research study.

Name and Signature of participant _____ Date_____

Name and signature of investigator _____ Date _____

Name and signature of witness _____ Date _____
(if required, as in case illiterate participants and consent by LAR)