Study title: "What are women's experiences of receiving mental health support during the perinatal period?"

Participant Information Sheet

Introduction

We are a team of perinatal mental health researchers at the University of Exeter Mood Disorders Centre. We are interested to know about your experiences with any mental health services or peer support groups during either your pregnancy or in the year after you gave birth to your child. This could involve your referral, the first assessment and/or any treatment you received. This project is being carried out across England with the University of Exeter.

Across England up to 30 women will be interviewed about their experiences of receiving mental health support.

We would like to invite you to take part in this research. However, before you decide whether or not you would like to take part we would like you to understand why we are carrying out this research and what it would involve for you. Please read this information sheet carefully. If you are interested in participating or you have any questions please contact me on the number given at the end of this sheet. Before you give your consent to take part (if you decide to do so) one of our team will go through the information sheet with you and answer any questions you might have. Please talk to others about the study if you wish.

Part One: Main Details about the Study

The purpose of the study

Research suggests that psychological therapies are effective at treating perinatal depression and anxieties. Sometimes the way treatments are offered in "real-world" health settings may not be as acceptable or effective as they are in research trials. We currently don't know if the various psychological treatments for depression and anxiety during pregnancy and the postnatal period is effective and acceptable to women and their families We are particularly interested in whether peer support from third sector organisations are effective and if women find these useful without the intervention of the NHS. Therefore, we would like to interview women who have experienced perinatal-specific treatment to find out more about their experiences. We hope that our findings will allow NHS services and charities to be better informed about what aspects of their perinatal provision works well, and any improvements that need to be made. We hope this will help to ensure that women receive the best possible experience of perinatal treatment.

Why have I been invited?

You have been invited to take part in this study because you are someone who has received treatment for perinatal depression and/or anxiety. You may have seen flyers about the study and responded to them, or you may have received an invitation to learn more about the study from a service you have contact with.

Do I have to take part?

It is entirely up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You will be free to withdraw at any time. You do not have to give a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care that you receive now or in the future within the NHS or elsewhere and will not affect your legal rights.

What does taking part involve?

Stage 1: finding out if the study is right for you

Firstly, we will run through this information sheet with you and give you the opportunity to ask any questions that you may have and we will do our best to answer them. Then, if you decide that you would like to take part, you will be asked to fill in and sign a consent form. You will be able to sign the consent form online, via a link we will text or email to you, or you can sign it in ink on a paper copy if you choose.

Stage 2: the study period

The study will consist of one interview lasting up to 1 hour. We will ask you questions about your experiences of receiving treatment during the perinatal period, including questions about the referral and assessment process, how suitable the treatment was for your problems, how suitable the delivery method was, and the quality of your assessor and/or therapist's perinatal knowledge.

The interview will take place either over the telephone or in a mutually agreed confidential location (e.g., home, quiet room at library) which is convenient for you.

Storing your data

We will take steps to keep your data confidential. If you choose to participate in the study, we will create an "identification code" for you. This will be a 4 digit number. We will store any recordings or clinical data on a secure password-protected University server, using only your 4-digit number. We will never store your recordings or clinical data using your name or contact details. During the course of the study, we will keep a master document that has only your name, contact details and 4-digit number. This master document will be stored separately from your recordings and clinical data also on a password-protected University server, and will be destroyed at the end of the study.

Audio-recording

At the start of the study you will be asked whether you would be willing for your interview to be audio-recorded. These recordings will be transcribed and form the data for the study. We will securely destroy the recordings once they are transcribed and checked for accuracy, and we will keep any identifying information separate of your transcription (and any identifying information will be removed from the transcript?). At any point during the conduct of the study, you can ask for the recordings or transcripts to be destroyed. You and your data collected will not be able to be recognised in any of the write up of the research to protect your confidentiality. At the end of the study, we will also destroy your identifying information (i.e. name, contact details).

<u>Part Two: Additional Information about the Study</u>

Will my taking part in this study be kept confidential?

All information that is collected as part of this research project will be kept confidential within the research team. Confidentiality would only be broken in exceptional circumstances, for example if it is felt by the researcher or therapist that you or someone else may be at immediate risk. In such circumstances it may be necessary for us to inform another person(s), for example your GP, but as far as possible we will do this in discussion with you.

We will keep electronic copies of the transcripts on password-protected university servers for 10 years from publication of the research or the last request for the data. With your permission, the anonymised clinical data collected in the research may be assessed by other researchers. We will not release transcripts of the interviews to other researchers outside the team in any form. We will only release numerical data that does not have any identifying data attached to it. Access to this numerical database will be controlled by investigator Dr Heather O'Mahen at the University of Exeter.

It will not be possible to identify you from any reports that we produce about the findings of the study. This may include quotations from interviews but these will not identify individuals and we will remove any contextual details that may reveal your identity (for example, city, schools, etc.). The report of the research will be available to members of the public including all the other participants in the study.

Are there any possible disadvantages or risks of taking part?

As participation in the study will only be for one hour, we do not anticipate significant risks or burdens as a result of taking part. However, interviews may cover sensitive issues, recalling experiences at a time in which you were experiencing mental health problems which may cause you to feel upset. If this happens we can stop the interview, it will then be up to you to decide if you wish to continue or whether you wish to stop the interview completely. You are not required to share information that you do not wish to and you may choose not to answer a question at any time. At the end of the interview you will be provided with a list of helpful contacts, which may be useful to contact in the case of any distressing issues arising which you feel that you need to discuss, including Netmums, Samaritans, IAPT, Bluebells (Bristol), MIND and the Maternal Mental Health Association.

Are there any benefits of taking part?

You will have the opportunity to give feedback on your experiences of receiving perinatal treatment within a possible range of services. Although you may not benefit directly form the information gathered, it is hoped that the data will go towards improving the services offered to women in their perinatal period. This may benefit future users. Dr. O'Mahen is involved regionally and nationally in perinatal initiatives, and she will feed back the overall results of this study to her colleagues at NHS England and National IAPT.

What will happen if I don't want to carry on with the study?

You may stop taking part at any time without having to give a reason, if so you can reach one of our researchers and state that you no longer want to be involved and any data you may have already provided will be destroyed. If this data was in a focus group has already been written up in analysis then as stated before any identifying information will not be involved so we may not be able to identify which participant said what and this information will be kept. However, anything that can be identified will be destroyed.

Are expenses covered?

You will not receive any payments for taking part however we aim to ensure that the interview process is cost free as we will travel to your preferred location e.g. your home, or telephone you so that you don't face any costs for taking part.

What will happen to the results of the study?

The researchers aim to publish the work in an academic journal and to report the findings at academic/clinical conferences. We will also provide all participants the opportunity of a summary of the results of the research, which will be given to the organisations who assisted with advertising our study. Generally our research is reported on the University of Exeter Mood Disorders Centre website at: http://www.centres.ex.ac.uk/mood and the Lancaster University Spectrum Centre for Mental Health Research website at: www.spectrumcentre.org. Findings may also be shared in publications for non-academic audiences including relevant voluntary sector newsletters/magazines. Your identity will not be revealed in any report or publication.

The longer term aim of this research is to inform government and services on how improve access to perinatal services for women.

Who is organising and funding the research?

The research sponsor is the University of Exeter. The researchers will not obtain any payment for conducting this research above their usual salaries. Part of this research will go towards an educational project for members of the research team (Chloe Rice and Emma Ingram).

Who has reviewed the study?
This study has been reviewed by Chair of Psychology Ethics Committee: Dr Nick Moberly (n.j.moberly@ex.ac.uk).

GDPR legal basis of processing:
The University of Exeter processes personal data for the purposes of carrying out research in the public interest. The University will endeavour to be transparent about its processing of your personal data and this information sheet should provide a clear explanation of this. If you do have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing dataprotection@exeter.ac.uk or at www.exeter.ac.uk/dataprotection.

Contact for further information

If you would like any independent advice about participating in research you can contact INVOLVE at www.invo.org.uk

If you have any further questions please contact the Chief Investigator, Dr Heather O'Mahen (01392724651, h.omahen@exeter.ac.uk) or one of the researchers Chloe Rice (csr215@exeter.ac.uk) or Emma Ingram (emi202@exeter.ac.uk)

What to do if you have a concern or complaint

If you have any concerns about the study then please contact the Chief Investigator and if you have any complaints about the study, please contact the Research Ethics and

Governance team at the University of Exeter. Gail Seymour – Research Ethics and Governance Manager (01392 726621, Email: g.m.seymour@exeter.ac.uk); or Pam Baxter – Senior Research Governance Officer (01392 723588) Email: p.r.baxter2@exeter.ac.uk