Study title: Understanding suicidal thoughts and behaviours in the perinatal period using common assessment measures: views of women and healthcare professionals

Short title: Perinatal participation in suicide-focused research

Participant Information Sheet (PIS): Participants

You are being invited to take part in a research study which is part of a PhD project exploring the most appropriate ways to conduct research about suicide, with women who are either pregnant or have given birth in the last 12 months. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part, and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

About the research

Who will conduct the research?

Kerry Hozhabrafkan (PhD student/lead researcher)
Division of Psychology and Mental Health, University of Manchester

Dr Sarah Peters (Senior lecturer and Health Psychologist)
Division of Psychology and Mental Health, University of Manchester

Dr Patricia Gooding (Senior Lecturer in Psychology)
Division of Psychology and Mental Health, University of Manchester

Dr Anja Wittkowski (Senior Lecturer in Clinical Psychology and Clinical Psychologist)
Division of Psychology and Mental Health, University of Manchester

What is the purpose of the research?

Having thoughts about suicide can affect anyone at any time in their lives. However, we know that for some women, these feelings arise for the first time or become more severe in pregnancy and/or in the year after birth. It is important to conduct research into this issue, so that preventative and treatment interventions can be developed to help. The aim of this study is to understand what women think about some of the suicide questionnaire measures that are currently used to measure suicidal experiences. We would also like to explore what it is like to take part in this type of research and to explore views on what researchers can do to make the experience appropriate and acceptable for pregnant and postnatal women.

You have been invited to take part because you have reported having suicidal experiences and you are currently either pregnant or have given birth in the past year. We intend to recruit 40 women to participate in the study.

Am I suitable to take part?

We are inviting people to take part who:

- Are pregnant or have given birth in the last year

  AND

- Have experienced suicidal thoughts or acts (at any time in the past)

Will the outcomes of the research be published?

It is anticipated that this study will provide evidence about appropriate and acceptable ways to ask women about their suicidal experiences in research studies. These findings will form part of the lead researcher's PhD thesis. They may also be presented at scientific research meetings and conferences and be published in academic journals. We will offer to send you a summary of the research findings and will need your postal or email address to do so if you would like this to happen.

Disclosure and Barring Service (DBS) Check

Kerry Hozhabrafkan (researcher) has undergone a satisfactory DBS check as determined by the School of Health Sciences and carried out by the University of Manchester

Who has reviewed the research project?

The study has been reviewed by an NHS Research Ethics Committee (East Midlands – Leicester Central, Ref: 22/EM/0073) and approved by the Health Research Authority (HRA).

Who is funding the research project?

This research project is being funded by Mental Health Research UK

What would my involvement be?

What would I be asked to do if I took part?

The researcher will arrange a mutually convenient time and place for a one to one discussion to take place with you. This could be in a specific room at the University of Manchester, at a health centre or in your own home. If you are currently an inpatient in a Mother and Baby unit, the discussion may take place there. You may also choose for the discussion to take place using video calling. The researcher will answer any questions you may have and will ask you to confirm verbally (recorded) or by signing a consent form that you wish to take part. Your involvement is expected to take up to

1.5 hours. Before beginning, the researcher will collect some details about you such as your age, ethnicity and family situation and about any mental health diagnoses you may have.

The first task you will be asked to do, is to complete a series of suicide questionnaire measures and to speak aloud what you are thinking as you do so. The researcher will make notes as you do this. After, the researcher may ask you to clarify any of the thoughts you were having that may not have been easy to observe at the time. For the final part of the process, the researcher will ask you a series of questions to find out what you thought about the suicide questionnaires and how it felt to complete them. The process will be audio recorded to help with later analysis. The researcher will want to monitor how you are feeling throughout your participation by asking you about your mood both before and after. Before leaving, you will be given the opportunity to ask any questions and provided with information about sources of support available should you need it. The researcher will also ask for your permission to contact you the next day via phone or email, to check on how you are feeling.

One week later you will be invited (via email) to complete an online survey. The survey will ask you some questions about how you have been feeling since taking part, any opinions about the procedures used and about your overall experience of participation. This should take no more than 30 minutes to complete.

What is the duration of the research?

We expect the total time it will take for you to participate in the study (including instructions before completing the questionnaires, discussions afterwards and completion of the survey) will be approximately 2 hours. This consists of a single session for the questionnaires/discussion on one day and completion of the survey one week later.

What are the risks and benefits of taking part?

You will be asked about your suicidal experiences (e.g. thoughts, plans, acts) by the researcher and as part of the questionnaires during the process. As a result, you may become upset or distressed. If this does happen we will take steps to support you. This might include:

- Pausing the discussion and suggesting a break
- Re-assessing whether you wish to continue participating
- Checking if you might want assistance with contacting a trusted friend/family member for support
- Discussing with you the possibility of contacting a healthcare professional for support
- Asking you questions to ensure your safety

If during the course of the study we have concerns about your safety or the safety of others we will:

- Ask you further questions about your thoughts/intent/plans to understand the level of risk to you or to others
- Discuss with you the need to pass on these concerns to others i.e. your named healthcare professional and the researcher's clinical supervisor within the study team

- Support you to seek help from your named healthcare professional and if appropriate a trusted friend or family member
- Signpost support services you can access
- If it is felt that you are at immediate risk of harm, we will remain with you until further help is available e.g. a healthcare professional or emergency services if necessary.

The researcher will aim to work collaboratively with you and will discuss actions to be taken with you first.

You may also find that taking part in this type of research has some personal benefits that are felt. However, this cannot be guaranteed.

Harm

In the unlikely event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester and [NHS trust] but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you

Will I be compensated for taking part?

You will receive a £10 gift voucher as a thank you for your time

What happens if I do not want to take part or if I change my mind?

It is up to you to decide whether or not to take part. Please contact the researcher (Kerry Hozhabrafkan) using the details listed below. If you do decide to take part, you will be given this information sheet to keep and will be asked to give verbal consent or to sign a consent form. Audio recording of the process is essential for the study, however you should feel comfortable with the recording process at all times and you are free to stop recording at any time. If you decide to take part, you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised (beyond two weeks after your involvement). This does not affect your data protection rights. If you decide not to take part you do not need to do anything further.

Your capacity to provide consent to take part in the study will be established prior to us asking you to do so. Once you have participated and we have included your data within the study, your ongoing capacity will be presumed and you data will not be removed from the study unless you specifically request this within the first two weeks.

Data Protection and Confidentiality

What information will you collect about me?

In order to participate in this research project we will need to collect information that could identify you, called "personal identifiable information". Specifically we will need to collect:

- Name
- Contact details
- Age
- Ethnicity
- Named healthcare professional contact
- Highest level of education
- Whether you are pregnant or have recently given birth
- Number of children and ages
- Mental health service use
- Mental health diagnoses
- Mental health problems experienced
- Suicidal experience history (thoughts/plans/acts)
- Audio recording of your voice speaking with the researcher

Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

What are my rights in relation to the information you will collect about me?

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you, including audio recordings.

Sometimes your rights may be limited if it would prevent or delay the research. If this happens you will be informed by the research team.

If you would like to know more about your different rights or the way, we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research or visit https://documents.manchester.ac.uk/display.aspx?DocID=37095

Will my participation in the study be confidential and my personal identifiable information be protected?

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

Audio recordings

The process will be recorded on an encrypted audio recording device and will be transferred on to the Manchester of University's secure server as soon as possible. Until this time the device will be kept in a securely locked location. The recording will then be used to produce a transcript. The recording will be listened to by the research team and may be listened to by a transcription service that is provided externally, but is under contractual agreement with and has been approved by the University of Manchester. Once transcription has been completed the recording will be permanently deleted from the recording device.

Online participation

Your participation in this research will be recorded in Zoom and your personal data will be processed by Zoom. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the United Kingdom to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place. The recordings will be removed from the above third party platform and stored on University of Manchester managed file storage as soon as possible following the completion of data collection.

Data confidentiality and storage

- The research team at the University of Manchester will have access to your personally identifiable data. We will assign a unique participant ID to your study data, this means that your personal details will be kept separate to your study data. It will not be possible to link the two without access to the key which will be created within a separate file. The key will be stored securely and separately from any other research data.
- Two weeks following your participation, the key will be securely destroyed, meaning the data will become fully anonymised.
- Personally identifying information e.g. name, contact details will be stored securely in a password-protected file on the University of Manchester server.
- Any potentially identifying information will be removed from the transcribed data as soon as possible following transcription.
- Direct quotes may be used in the study write up but they will not contain any information which could link them to you
- Transcribed data and online survey data will be stored securely on the University of Manchester server.
- Paper documents containing any of your personally identifiable data e.g. consent forms, will be stored in a locked cabinet in the researcher's office at the University of Manchester.
- Research data (transcripts and survey answers) will be kept for a minimum of 15 years following publication after which point it will be securely deleted.
- Consent forms/audio recorded consent will be stored separately from the main study data and will be kept for a minimum of 5 years before being deleted/securely destroyed.

- Your contact details will be deleted as soon as they are no longer required for the study i.e. when your involvement in the study ends, unless you agree for us to retain them to contact you in future about other studies. This would be for a maximum of 3 years. If you provide consent for this, your details will be safely stored on University of Manchester servers in a digital folder only accessible to the study team and used only for the purposes described above.

Sharing data

When you agree to take part in this study, we will ask for your consent for the data we collect (transcripts of audio recordings and survey responses) to be made available to other bona fide researchers to use. This means that they could use your data to conduct further research of their own. The data would be fully anonymised and would not contain any identifiable information. Your personal data would **not** be shared and it would not be possible for anyone using the study data to identify you or to attempt to contact you.

If you would like more general information on how researchers use data about patients, please visit: www.hra.nhs.uk/information-about-patients/

Please also note that individuals from the University of Manchester, NHS or regulatory authorities may need to look at the data collected for this study to make sure that the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

What if I have a complaint?

Contact details for complaints for NHS trusts

BTHFT patient experience team (Bradford Royal Infirmary): Tel - 01274 364810, Email – patient.experience@bthft.nhs.uk

BDCT patient advice and complaint department (Bradford community based services): Tel – 01274 251440, Email – advice.complaints@bdct.nhs.uk

If you have a complaint that you wish to direct to members of the research team, please contact:

Dr Sarah Peters (Senior Lecturer)
Telephone: 0161 2752558
Email: Sarah.Peters@manchester.ac.uk

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information Tel 0303 123 1113

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact the researcher(s)

Kerry Hozhabrafkan (PhD student/researcher)
Phone: 07587915084
Email: Kerry.Hozhabrafkan@postgrad.manchester.ac.uk

Additional information in relation to COVID-19

Due to the current COVID-19 pandemic, we have made some adjustments to the way in which this research study will be conducted that ensures we are adhering to the latest government advice in relation to social distancing as well as taking all reasonable precautions in terms of limiting the spread of the virus. You should carefully consider all of the information provided below before deciding if you still want to take part in this research study. If you choose not to take part, you need to inform research team. If you have any additional queries about any of the information provided, please speak with a member of the research team.

Are there any additional considerations that I need to know about before deciding whether I should take part?

If you decide to take part in person, you should consider the location and venue where the discussion is due to take place. It may be that you need to use public transport to travel to the venue. The venue itself (e.g. University campus/NHS premises) might be a particularly busy environment. This would mean that you are likely to encounter larger numbers of people and the level of risk in relation to Covid-19 transmission might be greater.

You should assess the level of personal risk and acceptability to you before deciding to participate in person and should not take part in this way if you have symptoms of Covid-19.

What additional steps will you take to keep me safe while I take part?

We will ensure that you will not be expected to come into contact with other research participants as meetings will be conducted on separate occasions. We will provide you with a single use pen to use during your participation. The research team will comply with venue specific Covid-19 policies designed to minimise the spread of the virus e.g. wearing of face covering in public areas, frequent hand washing/use of sanitiser, ensuring adequate ventilation and that rooms have been cleaned between each use.

Is there any additional information that I need to know?

We would ask that you do not arrive early at any venue where your meeting will take place.

What if the Government Guidance changes?

If government guidance changes to mean that you and/or the research team are not permitted to travel or to undertake this type of activity, then we will contact you to discuss either postponing your participation or conducting the meeting remotely.

What if I have additional queries?

Please contact Kerry Hozhabrafkan: Kerry.Hozhabrafkan@postgrad.manchester.ac.uk