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Evaluating the CORE-10 as a measure of psychological distress in women three months after miscarriage

WP2: Acceptability of the CORE-10

Introduction
We would like to invite you to take part in a study that aims to explore the acceptability and feasibility of using the CORE-10 questionnaire to assess psychological distress following miscarriage.

Before you decide if you want to take part, please read the following information carefully and ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

We know that suffering a miscarriage can affect the mental health of women but there is currently no standard way of testing this after miscarriage. In an earlier part of this study we tested how accurate the CORE-10 questionnaire was at identifying women with psychological distress following miscarriage. It is important to us to test whether the CORE-10 questionnaire is an acceptable way of testing women for psychological distress following miscarriages in the future.

Why have I been chosen?
We are inviting some participants who have completed the CORE-10 questionnaire in an earlier part of the study to help us to understand how acceptable the CORE-10 questionnaire is at assessing psychological distress in women after miscarriage.

Do I have to take part?
It is up to you to decide whether or not to take part. If you decide to take part we will ask you to sign a consent form. If you decide part way through the discussion that you do not want to carry on you do not have to. Similarly, if you do decide to take part, you will be able to withdraw from the study at any time and without giving a reason, and without any effect on the medical care that you receive but we will keep information about you that we already have. 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.

What do I have to do?
Taking part in the study involves completing some feedback using a likert scale about how you found completing the CORE 10 questionnaire and in the interview we will discuss your experience of completing the CORE-10 further. We will arrange to talk to you at a time and place convenient for you. You can choose to participate in the study via videoconference on Zoom or Teams or through a telephone interview. If you choose to take part, our discussion will last for about 45-60 minutes and will be audio recorded. All audio recordings will be stored digitally. These recordings will then be transcribed for the purposes of publishing the study findings. The audio recordings will be permanently removed after data analysis. No publication or report will identify you or anyone else by name.

How will we use information about you?
We will need to use information from you and the interview for this research project.

This information will include your initials, name, background information, NHS number, contact details, and information from the interviews. 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 contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

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.

Where can you find out more about how your information is used?
You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to dataprotection@contacts.bham.ac.uk

What are the possible disadvantages or risks of taking part?
We expect that there will be minimal disadvantages or risks of taking part. As this interview may be a few months following your miscarriage, it can potentially be triggering. We try to minimise any distress by offering telephone or video-conferencing and will aim to arrange your interview at a time that best suits you. If you experience distress at any point during the interview we can pause or stop with no pressure at all. We can also provide you with further support and linked services.

Where required, you are free to stop taking part in the study at any time. You are also welcome to contact the study team and the support organisations on the last page. If we are worried about your safety we will need to share this information with your GP and relevant health professionals.

What are the possible benefits of taking part in this study?
We do not know whether you will benefit personally from taking part in this study but we hope the information you share during your interview will help us to understand if this should be incorporated into standard care for women having a miscarriage nationally.

Confidentiality
All the information we obtain will be treated as confidential. Only the research team will have access to your personal data, and this will not be passed onto any outside bodies. Any information stored on a computer will be password protected. All participants will be given an identification number and this number will be used to link all data provided by each individual. When our discussion is transcribed all identifying details will be removed.

In case of concerns:
If you are concerned about any aspect of the research you can contact the team using the details below. If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, and you feel unable to discuss this with the research team then you may contact the University of Birmingham Research Governance Team by email on researchgovernance@contacts.bham.ac.uk .

What will happen to the results of this study?
We intend to use the information we have collected in this study to help develop an implementation strategy for wider adoption of the CORE-10 questionnaire in assessing women after miscarriage. This information will be shared with relevant health organisations, at academic meetings, and will be published in medical journals.

The results will also be used to design new materials specific for early pregnancy assessment unit (EPAU) settings. You will not be identified in any report/publication. We will send you the results of the study if you request this. Anonymised data used in this research project may also be used in future projects that are closely related to this project, or in the same general area of research as this project. All data of this project will be held under the provisions of the 2018 Data Protection Act including the General Data Protection Regulation (GDPR) which sets a standard for participant rights regarding their data. Data will be stored in manual and/or electronic files in a secure format for up to 10 years after the study has ended.

Who is organising and funding this research?
The study is sponsored and insured by the University of Birmingham.

The study has received ethical approval from the West Midlands - South Birmingham Research Ethics Committee, REC Ref 16/WM/0423.
This research is funded by Tommy's pregnancy and baby loss charity.

Who can I contact if I have any concerns about the project or want further support?
We hope that this information sheet answers all of the questions you might have. If you have any further questions or have found any aspect of this study distressing and need support please don't hesitate to contact the research team or any of the support organisations listed below with contact details.

E - tommys@contacts.bham.ac.uk

Dr Rosinder Kaur: PhD student; University of Birmingham; Email: rxk193@student.bham.ac.uk

Mr Lee Priest: Team Leader; University of Birmingham; Email: l.priest.1@bham.ac.uk

Tommy's pregnancy loss charity helpline , Telephone 0800 014 7800 (Monday to Friday, 9am to 5pm), or email us at midwife@tommys.org.

Thank you for taking time to consider taking part in this research, please keep hold of a copy of this information sheet for your records.