TRUST LOGO HERE	CORE-10 UNIVERSITY OF BIRMINGHAM Tommy's National Centre for Miscarriage Research

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

PATIENT INFORMATION SHEET WP1

Local Principal Investigator: [Insert name]

Local Research Nurse: [Insert name]

Telephone number: [Insert local number]

Email address: [Insert local email address]

Thank you for taking the time to read this information sheet. We understand that this might be a difficult time for you. This leaflet will provide more information about a research study that you can decide to take part in to try and help us find out which is the best way to help women who are in your situation.

We are sorry for your loss. We know that you may need extra support and so at the end of this leaflet we have provided the contact details for organisations that can help you.

Brief summary

We would like to invite you to take part in our research study. Joining the study is entirely up to you. Before you decide we would like you to understand why the research is being done and what it will involve for you. A member of our research team will go through this with you, to help you to decide whether or not you would like to take part and to answer any additional questions you may have. Please feel free to talk to others about this study if you wish.

The trial is informed by patient and public representation throughout the design, conduct, reporting and dissemination. This Patient information sheet tells you the purpose of the study, what will happen to you if you take part and detailed information about the conduct of the study. Please do 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?

We know that having a miscarriage is a traumatic and distressing event. It is common to feel like this, for most women this starts to improve after a few weeks. However, for some women, pregnancy loss may be part of what causes a mental health problem—or makes one worse.

At the moment there is no routine follow-up appointment for women who have suffered an early pregnancy loss. Nor is there a validated way of identifying those women that need more support or help from a mental health specialist.

We want to test the accuracy of a questionnaire that women can fill out (known as the CORE-10 assessment measure) at identifying those women that may be at risk of developing more prolonged psychological distress.

Taking part in the study involves completing the CORE-10 assessment and taking part in up to 2 interviews.

Do I have to take part?

Participation in our study is entirely voluntary. If you decide to take part, we will check you are eligible and you will be asked to sign a consent form. 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 at any time and without giving a reason, and without any effect on the medical care that you receive.

What is the CORE-10 assessment measure?

The CORE-10 is an easy-to-use assessment measure that consists of 10 questions and takes on average 2 minutes to complete. It is an easy-to-use assessment measure for common presentations of psychological distress, designed to be used for screening as well as over the course of treatment to track progress.

The measure is a shortened version of the 34 item CORE-OM, both of which ask respondents to self-report symptoms over the past week.

When should I take the assessment?

Prior research tells us that three months after miscarriage is the timepoint where we are more likely to identify those women that need further support or referral to mental health specialists.

How can I complete the assessment?

The assessment can be completed by you online. You will be asked to complete the questions based on how you've felt over the last week. We will email and/ or text you a link to complete the survey. It should take 2-3 minutes to complete. If this is difficult for you we will try our best to offer you an appointment where this can be completed at the hospital with the support of staff. We may also ask you to complete a baseline questionnaire collecting some background and demographic data. This may be completed by you via an online form or on your behalf by a member of the local research team.

Will my GP be notified?

Your GP will be notified that you are taking part in this study. If your result shows that you are experiencing distress we will contact you and notify your GP for further support and management. The next steps will vary according to your individual situation but you will be supported. If there are concerns that you need urgent help a health care professional will contact you.

What happens after the assessment? Everyone taking part in the study who completes the CORE-10 assessment will have an interview with a SCID (structured clinical interview for DSM-5 disorders) trained individual. The SCID is a diagnostic clinical interview for mental health disorders listed in the diagnostic and statistical manual (DSM-5). The interview takes on average 1-1.5 hours and includes questions related to mental health conditions (e.g. anxiety). This will not be audio or video recorded. This will take place over the phone or on a video call. If English isn't your first language we will try our best to offer an interpreter service to conduct the SCID in the language of your choice. A small number of interviews will be conducted by practitioners working outside of the United Kingdom but they will follow the same protocol and processes.

You are free to stop taking part in the interview at any time.

Anonymous quotes may be used in publications.

Some women may also be asked to take part in another interview to discuss their experience of completing the CORE-10.

What happens next?

If you agree to take part, you will be asked to sign a consent form and provide your email address and contact number. We will send you a link for the CORE 10 psychological assessment to be completed at three months and a reminder closer to the time.

How will information about me be collected?

We will collect most of our study information from the questionnaire, interview, your hospital notes and as part of any discussion with the care team.

What are the benefits of taking part in this trial?

At the moment there is not enough evidence to say whether the Core-10 is the best way of identifying women who have prolonged psychological distress following miscarriage.

We do not know whether you will benefit personally from taking part in this study, but the knowledge gained thanks to your help will inform future practice and potentially lead to improved detection of mental health problems for women after miscarriage in the future.

What are the risks of taking part?

Completing the assessment should not add further distress. There are no specific questions related to your miscarriage. However, the trained staff at each hospital will be guided by you and offer support as 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.

Can I decide not to carry on with the study?

If you decide to take part in the study but then change your mind, you will be free to withdraw at any time, without giving a reason (although we will appreciate it if you tell us why you changed your mind). Your care will not be affected in any way. You can stop being part of the study at any time, without giving a reason, 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 will happen to the results of the study?

When the results of the study are known, we will inform you of the overall findings by email and/or via our website. We will also publish the overall findings of the study in medical journal(s).

Who has organised and reviewed the research?

This study has been funded by Tommy's charity. It is sponsored and insured by the University of Birmingham, and data will be collected and stored by this institution.

The study has received ethical approval from the West Midlands - South Birmingham Research Ethics Committee, REC Ref 16/WM/0423. The doctors and nurses/midwives caring for you will not receive any payments for recruiting women into the study. Study participants will not be paid to take part. Your involvement would be greatly appreciated and will help us understand how best to identify those women that have prolonged psychological distress following a miscarriage and need further support.

What if there is a problem?

If you take part in the study, then you will retain the same legal rights as any other patient within the National Health Service. If you are not satisfied with any aspect of the way in which you have been approached or treated during the course of our study, then please speak first to the researchers (our contact details are on the front cover of this information leaflet).

If you wish to complain formally, then the normal National Health Service complaints mechanisms will be available to you.

Data Protection Essentials

How will we use information about you?

With your consent we will need to use information from you and your medical records for this research project.
This information will include your initials, name, background information, NHS number, contact details, information from the assessment and interviews,your medical history, pregnancy history, partner details and current medications. 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.

Who will my personal data be shared with?

[Insert NHS site] will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the University of Birmingham and regulatory organisations may look at your medical and research records to check the accuracy of the research study. [Insert NHS site] will pass these details to The University of Birmingham along with the information collected from you and your medical records. 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 to confirm any information or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. [Insert NHS site] will keep identifiable information about you from this study for 10 years after the study has finished. We will not share your personal data with any third party.

Once the study has been completed, anonymous data may be requested and shared with researchers running other research studies in this organisation and in other organisations for future research. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

How will my personal data be kept secure?

The University takes great care to ensure that personal data is handled, stored and disposed of confidentially and securely. Our staff receive regular data protection training, and the University has put in place organisational and technical measures so that personal data is processed in accordance with the data protection principles set out in data protection law.

The University has an Information Security Management System based on ISO27001 with a range of controls covering the protection of personal information. Annual security awareness training is mandatory for staff and the University is accredited under the NHS Information Governance Toolkit, the Payment Card Industry Data Security Standard and is in the process of gaining Cyber Essentials Plus for defined services. In relation to this project, electronic data will be kept on secure, encrypted IT servers within the University of Birmingham Any physical paperwork containing identifiable data will be kept in an access-controlled, secured room inside a locked filing cabinet at all times.

How long will my personal data be kept?

Your data will be retained for 10 years after the study has finished.

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

Where can I find more information?

If you have any questions about the study now or later, please feel free to ask the nurse or doctor named on the front page.

Sources of further support CONTACT INFORMATION

Local support can also be found through the NHS Patient Advisory and Liaison Service (PALS)

ATTACH LOCAL PALS
INFO STICKER HERE

Central support:

Tommy's www.tommys.org	midwife@tommys.org 0800 014 7800 Monday-Friday, 9-5pm
Miscarriage association	info@miscarriageassociation.org.uk 01924 200799 Monday-Friday, 9-4pm

If you would like to speak to someone about the study please contact the study team or access further information:

E – core-10@contacts.bham.ac.uk

https://www.birmingham.ac.uk/research/maternal-health/our-research