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Evaluating the CORE-10 as an assessment measure of psychological distress in women 3 months after miscarriage

Submission date
16/07/2024

Recruitment status
Recruiting

Registration date
06/08/2024

Overall study status
Ongoing

Last Edited
21/01/2025

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English Summary

Background and study aims
In the UK it is estimated that mental illness affects 1 in 5 women during pregnancy and after birth with a cost to society of £8.1 billion for every annual cohort of births. Miscarriage is defined as the loss of a pregnancy before viability, which in the UK includes pregnancy losses from conception until 23 weeks and 6 days gestation. Miscarriage is common with an estimated 23 million miscarriages occurring every year worldwide, translating to 44 pregnancy losses each minute.
Miscarriage can be a deeply distressing experience. The psychological impact of miscarriage can go unrecognised by healthcare professionals, family and friends. However, anxiety, depression and PTSD are all strongly associated with miscarriage. In 2020, a study of 537 women following miscarriage found that 9 months after a pregnancy loss, 6% of women met the criteria for moderate or severe depression, 17% for moderate or severe anxiety and 18% for post-traumatic stress. Identifying women at risk of psychological distress following miscarriage and the development of optimal treatment strategies have been recognised as research priorities. This study aims to evaluate the diagnosis accuracy of the CORE-10 online questionnaire in identifying women who meet the DSM-V diagnostic criteria for psychopathology.

Who can participate?
Women aged 18 years and over who have experienced an involuntary pregnancy loss (miscarriage <24 weeks, stillbirth, neonatal death, ectopic pregnancy, gestational trophoblastic disease [molar pregnancy], or recurrent miscarriage)

What does the study involve?
Work package 1: This work package will involve confirmation of any subsequent pregnancy since the miscarriage diagnosis was made, completion of the CORE-10 questionnaire and a diagnostic interview completed online via the online CORE-10 database.
Work package 2: About 40 women from WP1 will complete surveys and interviews to evaluate their perspective of the CORE-10 online questionnaire.

What are the possible benefits and risks of participating?
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.
It is not known whether participants will benefit personally from taking part in this study, but the knowledge gained will inform future practice and potentially lead to improved detection of mental health problems for women after miscarriage in the future.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
November 2023 to September 2025

Who is funding the study?
Tommy's (UK)

Who is the main contact?
core-10@contacts.bham.ac.uk

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

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
215646

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2.0 (28-Mar-2024), IRAS 215646, CPMS 32263

Study information

Scientific Title
Evaluating the CORE-10 as an assessment measure of psychological distress in women 3 months after miscarriage

Acronym
CORE-10

Study hypothesis
This work package aims to evaluate the diagnosis accuracy of the CORE-10 online questionnaire in identifying women who meet DSM-V diagnostic criteria for psychopathology.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/02/2024, West Midlands - South Birmingham Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8230; southbirmingham.rec@hra.nhs.uk), ref: 16/WM/0423

Study design
Observational study

Primary study design
Observational

Secondary study design
Diagnosis accuracy study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Condition
Miscarriage

Interventions
The Clinical Outcomes in Routine Evaluation (CORE-10) was suggested as a possible single tool to screen for psychological distress. There was an agreement amongst professionals regarding the availability and ease of use of the tool. CORE-10 is a strong tool for assessing psychological distress in women given its broad coverage of a range of constructs and familiarity with clinicians.

The CORE-10 online questionnaire is used to identify women who meet DSM-V diagnostic criteria for psychopathology. This work package will involve confirmation of any subsequent pregnancy since the miscarriage diagnosis was made, completion of the CORE-10 questionnaire and a diagnostic interview which are completed online via the online CORE-10 database (Redcap).

Intervention Type
Other

Primary outcome measure
Psychological distress is measured using the Clinical Outcomes in Routine Evaluation (CORE-10) online questionnaire, and completed by women 3 months following a miscarriage (work package 1). The CORE-10 questionnaire will be compared with the results of the clinical diagnostic interview (completed within 28 days from the date of the CORE-10 questionnaire).

Secondary outcome measures
The acceptability of the CORE-10 online questionnaire will be measured by survey, clinical interview and completion of a Likert Scale (work package 2). Forty participants will be randomly selected after the completion of the diagnostic clinical interview.

Overall study start date
11/11/2023

Overall study end date
30/09/2025

Eligibility

Participant inclusion criteria

1. Female
2. Primiparous or multiparous
3. Ability to provide written informed consent to take part in the study
4. Age ≥18 years old
5. Diagnosis of miscarriage ≤16+6 weeks (singleton or multiple pregnancies) acquired from hospital records
6. Recurrent or sporadic miscarriage

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
595

Participant exclusion criteria
1. Miscarriage ≥17 weeks
2. Other types of early pregnancy loss (e.g. gestational trophoblastic disease or ectopic pregnancy) acquired from hospital records
3. Termination of pregnancy
4. Prior enrolment in this study

Recruitment start date
07/08/2024

Recruitment end date
31/05/2025

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
NHS Grampian
Dugald Baird Centre

Aberdeen Maternity Hospital
Aberdeen
United Kingdom
AB25 2ZL

Study participating centre
Ashford and St. St. Peter’s Hospitals NHS Foundation Trust
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre

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Sponsor type
University/education

Website
http://www.birmingham.ac.uk/index.aspx

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Tommy's

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A manuscript will be submitted to peer reviewed publications. Through a variety of platforms, data will be shared with patients, commissioners, clinicians, third sector organisations and policy makers. A supplementary lay summary will also be provided within the report to ensure wide dissemination amongst clinicians, patients and the public. The study findings will also be presented at key international conferences. All publications will acknowledge participants and EPAUs. These dissemination strategies will ensure widespread disseminated to the NHS, wider public and researchers.

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from core-10@contacts.bham.ac.uk
The type of data that will be shared: Appropriate data-sharing requests will be considered by the trial management group and the Tommy's Management Centre. Any data shared will be anonymous.
Data will be stored securely in a redcap database on servers at the University of Birmingham. Personal data recorded on all documents will be regarded as strictly confidential and will be handled and stored in accordance with the General Data Protection Regulation, 2018.

IPD sharing plan summary
Available on request