

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/08/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/05/2025	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

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 April 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 objectives

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

Health condition(s) or problem(s) studied

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

Completion date

30/04/2026

Eligibility**Key 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 $\leq 16+6$ 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

Key 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

Date of first enrolment

07/08/2024

Date of final enrolment

31/12/2025

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. Peter's Hospitals NHS Foundation Trust

Ashford & St Peter's Hospitals NHS Foundation Trust
1st floor, Chertsey House
St Peter's Hospital
Guildford Road
Chertsey
Surrey
United Kingdom
KT16 OPZ

Study participating centre

Birmingham Women's and Children's NHS Foundation Trust

Steelhouse Lane
West Midlands
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B4 6NH

Study participating centre

Imperial College Healthcare NHS Trust

Praed Street
London
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W2 1NY

Study participating centre

King's College Hospital NHS Foundation Trust

Denmark Hill
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SE5 9RS

Study participating centre

University Hospitals Of Leicester NHS Trust

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Leicester
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LE1 5WW

Study participating centre
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Study participating centre
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Royal Preston Hospital
Fulwood
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United Kingdom
PR2 9HT

Study participating centre
South Tyneside and Sunderland NHS Foundation Trust
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Kayll Rd, Sunderland
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SR4 7TP

Study participating centre

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Sponsor information

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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