

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 10/12/2025	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 June 2026

Who is funding the study?

Tommy's (UK)

Who is the main contact?

core-10@contacts.bham.ac.uk

Contact information

Type(s)

Public, Scientific

Contact name

Mr Lee Priest

Contact details

Tommy's National Centre for Miscarriage Research (Birmingham)

WHO Collaborating Centre for Global Women's Health

School of Medical Science

Metabolism and Systems Science

University of Birmingham

Birmingham

United Kingdom

B15 2TH

N/A

l.priest.1@bham.ac.uk

Type(s)

Principal investigator

Contact name

Prof Arri Coomarasamy

Contact details

Tommy's National Centre for Miscarriage Research (Birmingham)

WHO Collaborating Centre for Global Women's Health

School of Medical Science

Metabolism and Systems Science

University of Birmingham

Birmingham
United Kingdom
B15 2TH
N/A
a.coomarasamy@bham.ac.uk

Type(s)
Scientific

Contact name
Dr Rosinder Kaur

Contact details
Birmingham Women's and Children's NHS Foundation Trust
Mindelsohn Way
Birmingham
United Kingdom
B15 2TG
N/A
rosinder.kaur@nhs.net

Type(s)
Scientific

Contact name
Dr Emily Fox

Contact details
Birmingham Women's and Children's NHS Foundation Trust
Mindelsohn Way
Birmingham
United Kingdom
B15 2TG
N/A
e.fox3@nhs.net

Type(s)
Scientific

Contact name
Dr Adam Devall

Contact details
Tommy's National Centre for Miscarriage Research (Birmingham)
WHO Collaborating Centre for Global Women's Health
School of Medical Science
Metabolism and Systems Science
University of Birmingham
Birmingham
United Kingdom
B15 2TH

N/A
a.j.devall@bham.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
215646

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2.0 (28-Mar-2024), 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

Study type(s)
Treatment

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(s)

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).

Key secondary outcome(s)

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.

Completion date

30/06/2026

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

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

100 years

Sex

Female

Total final enrolment

0

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

31/03/2026

Locations**Countries of recruitment**

United Kingdom

England

Scotland

Study participating centre**NHS Grampian**

Dugald Baird Centre

Aberdeen Maternity Hospital

Aberdeen

Scotland

AB25 2ZL

Study participating centre**Ashford and St. 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 NO COUNTRY SPECIFIED, assuming England
England
KT16 OPZ

Study participating centre
Birmingham Women's and Children's NHS Foundation Trust
Steelhouse Lane
West Midlands
Birmingham
England
B4 6NH

Study participating centre
Imperial College Healthcare NHS Trust
Praed Street
London
England
W2 1NY

Study participating centre
King's College Hospital NHS Foundation Trust
Denmark Hill
London
England
SE5 9RS

Study participating centre
University Hospitals Of Leicester NHS Trust
Kensington Building
Leicester Royal Infirmary
Leicester
England
LE1 5WW

Study participating centre
Shrewsbury and Telford Hospital NHS Trust
The Princess Royal Hospital,
Apley Castle,
Apley,

Telford
England
TF1 6TF

Study participating centre

NHS Lothian
Waverleygate
2-4 Waterloo Place
Edinburgh
Scotland
EH1 3EG

Study participating centre

Lancashire Teaching Hospitals NHS Foundation Trust
Womens Health Research Office
Ante-Natal Clinic
Royal Preston Hospital
Fulwood
Preston
England
PR2 9HT

Study participating centre

South Tyneside and Sunderland NHS Foundation Trust
Sunderland Royal Hospital
Kayll Rd, Sunderland
Sunderland
England
SR4 7TP

Study participating centre

University Hospitals Coventry & Warwickshire
Clifford Bridge Road
Coventry
England
CV2 2DX

Sponsor information

Organisation

University of Birmingham

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

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes