Peer support to improve mental health outcomes following miscarriage: a mixed methods study of effectiveness and experiences

Submission date	Recruitment status	[X] Prospectively registered
22/03/2024	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
26/03/2024	Ongoing	Results
Last Edited	Condition category	Individual participant data
22/08/2024	Mental and Behavioural Disorders	Record updated in last year

Plain English summary of protocol

Background and study aims

'Miscarriage' is the term used to describe the loss of pregnancy during the first 23 weeks. Experiencing miscarriage can be very traumatic. However, mental health support after miscarriage is not routinely offered by healthcare services.

Miscarriage 'peer support' links people with experience of miscarriage with others who have also experienced miscarriage, to provide support, hope and encouragement. Research evidence has shown that peer support after miscarriage can be helpful to parents (mothers and/or their partners) in reducing mental trauma.

This project will identify all miscarriage peer support interventions that have been written about, both in the United Kingdom and elsewhere in the world. We will then share this summary with people who both provide miscarriage peer support and people who have been offered miscarriage peer support, to compare what we have found with their personal experiences of support.

Who can participate?

We will seek a wide range of views from people including, providers from different NHS and charity organisations, and parents, aged 18 or older, who have experienced either a single or multiple miscarriage(s), within the last two years.

What does the study involve?

The study involves one-to-one interviews with a researcher to explore experiences of receiving or providing peer support following miscarriage. This will include questions such as how helpful the support was, and whether there were any barriers to taking up support and how support can be made better.

What are the possible benefits and risks of participating?

Although interviews will focus on experiences of peer support, this might bring up memories or thoughts about their miscarriage experience that participants may find upsetting or distressing.

Participants will be supported by the researcher and will not be asked to answer any questions they feel uncomfortable with.

Participants will be reimbursed as a thank you for their time. Participants may also gain satisfaction from participating in research and supporting the generation of new knowledge.

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

When is the study starting and how long is it expected to run for? March 2024 to May 2026

Who is funding the study? National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?

Dr Leanne Burton (Chief Investigator), lrburton@liverpool.ac.uk

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

337623

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 337623, NIHR 156802, CPMS 61892

Study information

Scientific Title

Peer support intervention to improve mental health outcomes in those who have experienced miscarriage: systematic review and evidence synthesis of effects, barriers and facilitators to inform service design

Study objectives

To explore, with parents offered peer support following miscarriage and miscarriage peer support providers, the acceptability and accessibility of peer support interventions.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 13/08/2024, University of Liverpool Research Ethics Committee (University of Liverpool, Liverpool, L69 3GL, United Kingdom; +44 1517942000; researchethics@liverpool.ac. uk), ref: 14413

Study design

Qualitative in-depth individual interview study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Mental health for parents following miscarriage.

Interventions

Qualitative in-depth interviews will be undertaken with 40 peer support recipients (30 mothers; 10 partners) and 20 peer support deliverers. Interviews will be conducted on an individual basis, in a setting that is suitable to the participant (either virtual or face-to-face) and will last approximately 60 minutes. Interviews will be semi-structured and will follow a topic guide which will guide the researcher through a number of topics.

Intervention Type

Other

Primary outcome(s)

Measured using qualitative in-depth interview at a single time point: Understanding of the acceptability and accessibility of peer support interventions to improve mental health outcomes in parents following miscarriage.

Key secondary outcome(s))

Measured using qualitative in-depth interview at a single time point:

- 1. Appropriateness of outcomes used to measure effectiveness of peer support interventions.
- 2. Perceived effectiveness of peer support following miscarriage.
- 3. Potential issues in measuring cost-effectiveness of peer support interventions.

Completion date

30/05/2026

Eligibility

Key inclusion criteria

Parents:

- 1. Age 18 years and over
- 2. Ability to give informed consent
- 3. Parents (mothers or partners) who have experienced miscarriage within the previous 2 years defined as loss of pregnancy before 24 weeks gestation and have been offered a peer support intervention in any setting.

Peer Supporters

- 1. Any person who has experience of delivering peer support to parents following miscarriage in any setting.
- 2. Peer supporters must have been involved in a peer supporter role for a minimum of three months.

Participant type(s)

Service user, Other

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Parents and Peer Supporters

1. Individuals who do not sufficiently understand verbal explanations or written information in English, or who have special communication needs

Date of first enrolment

01/01/2025

Date of final enrolment

30/04/2025

Locations

Countries of recruitment

United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre University of Liverpool

Department of Primary Care and Mental Health Institute of Population Health 2nd Floor, Block H, Waterhouse Building, Pembroke Place Liverpool United Kingdom L69 3GL

Sponsor information

Organisation

University of Liverpool

ROR

https://ror.org/04xs57h96

Funder(s)

Funder type

Government

Funder Name

National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

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 stored in a non-publicly available repository and are not expected to be made available due to the sensitive nature of the data and small sample size.

IPD sharing plan summary

Stored in non-publicly available repository, Not expected to be made available