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

Submission date
22/03/2024

Registration date
26/03/2024

Last Edited
22/08/2024

Recruitment status
No longer recruiting

Overall study status
Ongoing

Condition category
Mental and Behavioural Disorders

☒ Prospectively registered
☐ Protocol
☐ Statistical analysis plan
☐ Results
☐ Individual participant data
☒ 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
Dr Leanne Burton

ORCID ID
http://orcid.org/0000-0002-5870-4161

Contact details
University of Liverpool, Department of Primary Care and Mental Health, Institute of Population Health, 2nd Floor, Block H, Waterhouse Building
Liverpool
United Kingdom
L39 3GL
+44 1517957737
lrburton@liverpool.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
337623

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Qualitative investigation

Study setting(s)
Charity/Voluntary sector, Internet/virtual

Study type(s)
Other

Participant information sheet

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 measure

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.

Secondary outcome measures
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.

Overall study start date
22/03/2024

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

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
England

Northern Ireland

Scotland

United Kingdom

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

Sponsor details
University of Liverpool
Brownlow Hill
Liverpool
England
United Kingdom
L69 3BX

+44 1517942000
sponsor@liverpool.ac.uk

Sponsor type
University/education

Website
http://www.liv.ac.uk/

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

Publication and dissemination plan
There are 5 key audiences for this research, these are:
A. Patients and the public
B. Commissioning Organisations (Integrated Care Boards, NHS England, Maternal Mental Health Services)
C. Voluntary, community, faith and social enterprise (VCFSE) organisations
D. External statutory organisations (Department of Health, NICE)
E. Academia

To ensure that the outputs from this research inform policy and practice and therefore maximises benefits to patients, the NHS and VCFSE organisations, the following dissemination strategy has been developed. Below are the details of the main outputs. Although this proactive dissemination strategy offers breadth to reach out to multiple audiences, we anticipate this will adapt in consultation with the PAG and expand to other types of outputs we could use to engage and communicate to ensure we reach a diverse audience. Networks will be established throughout the life course of the study to further inform and strengthen the dissemination strategy.
Evidence suggests that research is most effectively disseminated using multiple vehicles. In addition to giving written feedback to all study participants, dissemination activities will include:

- A state-of-the-evidence report summarising key findings including a national and comparative international picture of the use of peer support interventions to support mental health outcomes in those experiencing miscarriage (A,B,C,D,E)
- Good practice guidance and recommendations to improve peer support delivery across the national landscape including report on FutureNHS platform (A,B,C,D,E)
- Peer-reviewed publications in high impact academic journals (systematic review protocols, at least 3 findings papers) and research summaries for professional periodicals (B,D,E)
- National conference presentations including NHS England Maternal Mental Health Service webinars (B,C,D,E)
- Full study report detailing the research, findings and its policy and practice implications (A,B,C, D,E)
- Social media (e.g. website and Twitter) to disseminate lay information about the study (A,C,E)
- Interactive one-day webinar to disseminate research findings to all which will be used to celebrate the study, thank participants for their contribution and discuss findings. (A,B,C,D,E)
- Development of a short animated video to describe findings of the study/ signpost people to services (A,B,C,D)

A one-day interactive webinar will focus on dissemination and discussion of the project findings. Academics, researchers, VCFSE organisations, health care professionals and the public will be invited, ensuring a range of voices and perspectives are present on the day. Within the webinar we will ensure that those affected by miscarriage are participating within the programme; their voices will be actively encouraged in considering the development and implementation of future peer support interventions.

Intention to publish date
30/04/2027

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