UNIVERSITY OF LIVERPOOL

NIHR Public Health Research (PHR) Programme

Peer support interventions to improve mental health outcomes after miscarriage: systematic reviews and evidence synthesis of effectiveness, and barriers and facilitators to inform future service design.

Study Protocol

V1.0

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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.

Short Title

Peer support interventions to improve mental health outcomes after miscarriage: evidence synthesis with a qualitative study.

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Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Signed by: Karen Jennings-Wilding
Signer Name: Karen Jennings-Wilding
Signing Reason: I approve this document
Signing Time: 04 September 2024 | 4:10:41 PM BST
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Date: 04 September 2024

Name (please print):

Mrs Karen Jennings-Wilding

Position:

Senior Clinical Research Governance Manager

Chief Investigator:

Signature: Signed by: Leanne Burton
Signer Name: Leanne Burton
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Sponsor	The University of Liverpool is the research Sponsor for this Study. It is recognised that as an employee of the University the Chief Investigator has been delegated specific duties, as detailed in the Sponsorship Approval letter. For further information regarding the sponsorship conditions, please contact: Mrs Karen Jennings-Wilding Senior Clinical Research Governance Manager Sponsor@liverpool.ac.uk
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Study Summary

Study Design	Mixed-methods –evidence synthesis supplemented with primary qualitative research.
Study Participants	**Evidence Synthesis (WP1)** The following studies will be included; **Population**: Parent(s) (i.e. women and birthing people or their partners) who have experienced miscarriage (loss of pregnancy before 24 weeks gestation) (R1, R2). Peer supporters who deliver/facilitate delivery of peer support following miscarriage (R2). **Intervention:** Peer support after miscarriage. **Comparator:** Any peer support intervention delivered to parents after miscarriage versus control (no treatment, wait list or usual care), any peer support intervention versus another psychosocial intervention, or no comparator. **Outcomes of Interest:** R1 (effectiveness) – studies that report any quantitative measure of the broad groups of the following outcomes; personal recovery, clinical recovery, health service utilisation, social support. **Phenomena of Interest:** R2 (barriers and facilitators) – barriers to and facilitators of implementation of peer support interventions to improve mental health outcomes for parents after miscarriage to both recipients and providers. **Context:** Peer support interventions that are organised and delivered in any setting. **Study Type:** R1- any primary research study design with an evaluative component. R2 – qualitative, quantitative and mixed-methods primary studies. **Qualitative Study (WP2)** Parents (women and birthing people (n=30); partners (n=10) 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 will be recruited through relevant patient charities. *Inclusion criteria* • Age 18 years and over • Ability to give informed consent • Parents (women and birthing people 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. *Exclusion criteria* • Individuals who do not sufficiently understand verbal explanations or written information in English, or who have special communication needs Peer supporters (n=20) (i.e. those who deliver peer support interventions) will be identified and recruited through VCFSE organisations and NHS service providers delivering peer support after miscarriage. *Inclusion criteria* • Any person who has experience of delivering peer support to parents in any setting • Peer supporters must have been involved in a peer supporter role for a minimum of 3 months. *Exclusion criteria* • Individuals who do not sufficiently understand verbal explanations or written information in English, or who have special communication needs.
Planned Size of Sample (if applicable)	**Qualitative Study (WP2)** 60 participants (30 women/birthing people, 10 partners, 20 peer supporters)
Treatment Duration	N/A
Follow up duration (if applicable)	N/A
Planned Study Period	24 months (1st May 2024-30th April 2026)
Research Question/Aim(s)	The study will address the research question: What is the effectiveness of peer support interventions to improve mental health outcomes for parents after miscarriage and what are the barriers to, and facilitators of these interventions to the population? **Objectives** The research aim will be met through the following four research objectives through two convergent parallel work packages (WP):

	(1) To systematically review evidence pertaining to the effectiveness of peer support interventions to improve mental health outcomes after miscarriage (WP1). (2) To systematically review published and unpublished literature on barriers to and facilitators of successful implementation of peer support interventions to improve mental health outcomes after miscarriage (WP1). (3) To conduct an overarching synthesis of (1) and (2) to integrate the findings by exploring whether the barriers and facilitators findings can help explain the effects (or lack of) of peer support interventions to improve mental health outcomes for parents after miscarriage (WP1). (4) To conduct an in-depth qualitative study to determine multiple perspectives on the findings from the systematic reviews and to explore, with parents offered peer support after miscarriage and peer support providers, the barriers to, and facilitators of, peer support interventions (WP2).

Funding and Support in Kind

FUNDER(S)	FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN
NIHR Public Health Research (PHR) award	**£460,657.30**

Roles and Responsibilities of Study Management Committees/Groups & Individuals

Study Steering Groups

The named co-applicants represent key stakeholders who will form the Project Management Group and support the day-to-day running of this study, ensuring its progress with the project plan and its conduct is in accordance with this protocol and Good Clinical Practice (GCP) guidelines.

In line with NIHR guidance, a Study Steering Committee and Data Monitoring and Ethics Committee have been established to have more general, independent oversight of the study and report back to NIHR.

Study Steering Committee members comprise key decision makers who are committed to providing support to the overall project on behalf of the Funder, to ensure rigorous study conduct in line with UK Policy Framework for Health and Social Care and the Guidelines for Good Clinical Practice (GCP). Study Steering Committee membership has been approved by NIHR.

Data Monitoring and Ethics Committee (DMEC) comprises independent members who are responsible for monitoring data collected as part of the study, making recommendations to the Study Steering Committee on

whether there are any ethical or safety reasons as to why the study should not continue, upholding the safety, rights and well-being of the study participants. DMEC membership has been approved by NIHR.

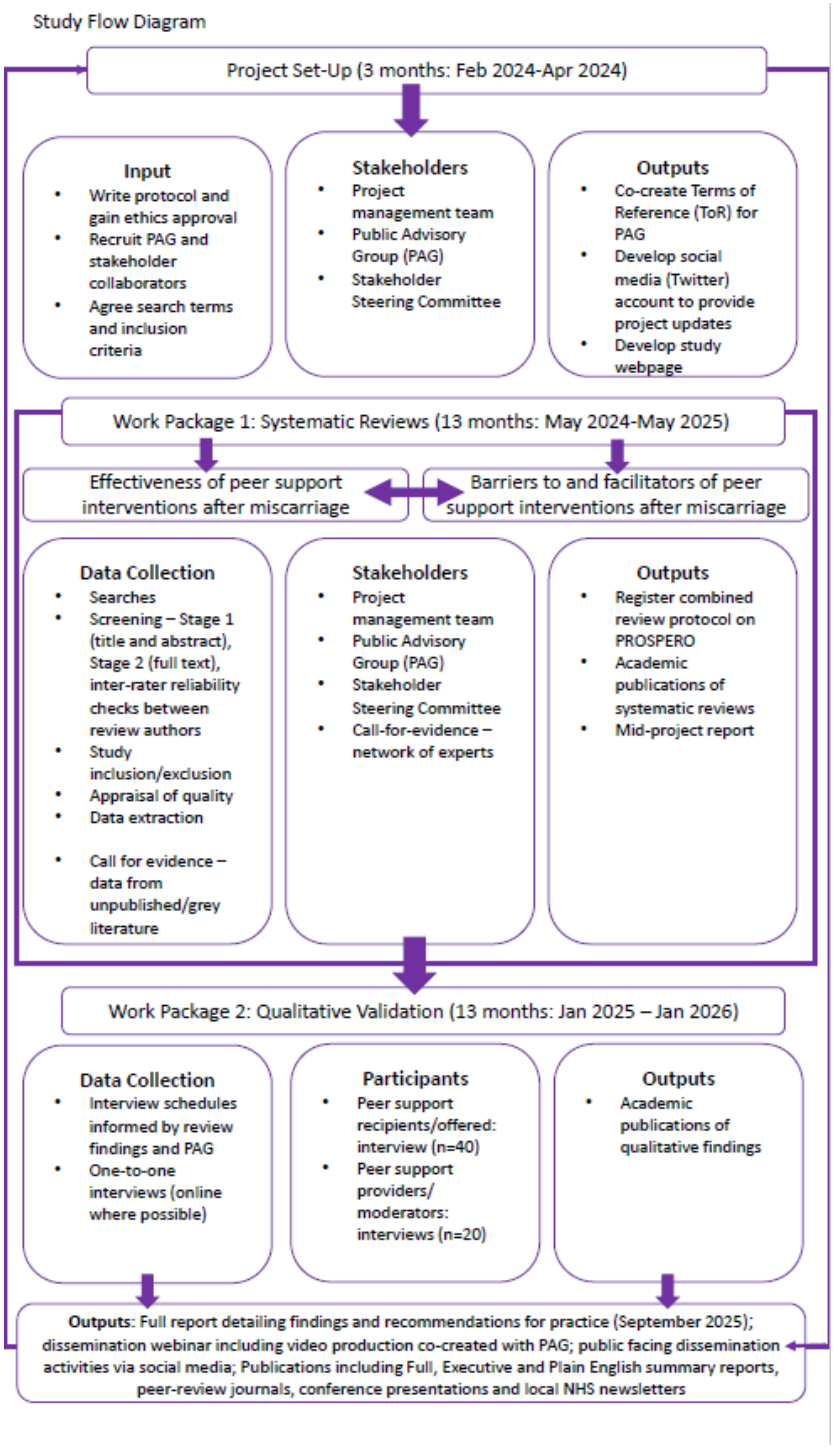
Patient and Public Involvement

People with lived experience of miscarriage have been actively involved in the development of this research proposal and are included as co-investigators on this project. A Public Advisory Group (PAG) (n=8) will be developed to contribute to the project, including reviewing and discussing recruitment processes, interview questions and contributing to dissemination plans. A Public Advisor (SL), alongside the PPI lead (SH) will lead and co-ordinate the PAG to ensure the perspectives of service users are embedded throughout the life of the study and beyond. Funding has been costed for PPI at INVOLVE recommended rates. The Health Inequalities Assessment Toolkit(1) will be used to consider and address health inequalities and access for people to peer support interventions after miscarriage.

The role and recruitment information for PAG members and co-investigator/stakeholder operating procedures will include a suggested procedure for emotional distress. This will include options to withdraw from or pause activities. For in-group activities/discussion, the facilitator (or PPI lead) will follow-up any stated distress, focusing on an offer of support. Signposting will be offered and if concerns are identified, the PI will be informed and a support plan, which could also include withdrawal from an adviser role or a pause, will be put in place.

Key Words: Parents; Miscarriage; Mental Health; Peer Support; Third Sector; Evidence Synthesis; Systematic Review; Qualitative

Study Flow Chart



Glossary of Abbreviations

UK	United Kingdom
PTSD	Post-Traumatic Stress Disorder
NHS	National Health Service
NICE	National Institute for Care Excellence
DHSC	Department for Health & Social Care
VCFSE	Voluntary, Community, Faith and Social Enterprise
RCT	Randomised Controlled Trial
PHR	Public Health Research
PAG	Public Advisory Group
HIAT	Health Inequalities Assessment Toolkit
CRD	Centre for Reviews and Dissemination
OCED	Organisation for Economic Co-operation and Development
MMAT	Mixed Methods Appraisal Tool
PDRA	Post-Doctoral Research Associate
JBI	Joanna Briggs Institute
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
EDI	Equality, Diversity and Inclusion
NHS REC	National Health Service Research Ethics Committee
R&D	Research & Development
GDPR	General Data Protection Regulation
ARISE	Applied Research, Innovation and Service Evaluation
LRiG	Liverpool Reviews and Implementation Group
ARC NWC	Applied Research Collaboration, North West Coast

Contents

1. INTRODUCTION

This protocol describes the Study entitled: "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". The protocol provides information about procedures for entering participants, study procedures, safety reporting and governance requirements. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the Study following receipt of required approvals.

Queries relating to this Study should be referred, in the first instance, to the Chief Investigator: Dr Leanne Burton, or the Joint Lead Investigator: Professor Elizabeth Perkins, via the contact details provided on page 5 of this protocol.

This study will adhere to the principles outlined in the UK Policy Framework for Health and Social Care Research. It will be conducted in compliance with the protocol, the Data Protection Act 2018 and the UK GDPR as amended from time to time and any successor legislation in the UK and any other directly applicable regulation relating to data protection and privacy as well as any other regulatory requirements as appropriate.

2. BACKGROUND

In the UK, miscarriage is defined as the spontaneous loss of pregnancy before 24 weeks(2). Miscarriage occurs in 15-30% of pregnancies, affecting 70,000–90,000 women in the UK each year(3), although true prevalence is likely to be to be much higher(4). True prevalence is difficult to predict due to many miscarriages being managed at home and therefore actual numbers of those affected by miscarriage is considerably higher. The minimum economic cost of miscarriage to the NHS is thought to be around £471 million per annum, though this only covers direct health services and lost productivity. It is expected to surpass £1 billion when including longer-term physical, reproductive and mental health impacts(5).

Miscarriage can be a traumatic event and have a detrimental impact on the psychological wellbeing of both women and their partners(6). Nearly 20% of women who experience miscarriage develop depression and/or anxiety and 28% suffer from post-traumatic stress disorder (PTSD)(7-9). Symptoms can persist long-term, impacting overall quality of life and subsequent pregnancies(10). A 2016 study found that four in ten women experienced PTSD symptoms within three months following either a miscarriage or ectopic pregnancy(8). A further study found that one in five mothers and one in twelve partners had long-term symptoms of PTSD after miscarriage, demonstrating the impact on both parents(11).

Poor maternal mental health has both immediate and long-term impacts on women's well-being. It limits opportunities for social and economic participation and reduces both self-care and subsequent care-giving capacity. Symptoms can persist long-term, impacting quality of life and subsequent pregnancies(10). Evidence suggests that even after having a subsequent healthy child, women who miscarry have a higher risk of experiencing postpartum depression(7). Similarly, fathers whose partners experience miscarriage are at risk of pronounced psychological impact. Assuming the role of 'protector' and 'supporter' of their partner, their own psychological needs are often overlooked, leading to a worsening of depressive symptoms(12).

While health professionals care routinely focuses on the physical effects of pregnancy loss, practices for psychological care appear to be significantly less well developed and less considered. According to the National Institute for Health and Care Excellence (NICE), grief following miscarriage is "*comparable in nature, intensity and duration*" to grief reactions in people suffering other types of major loss(2). Improving psychological

support after miscarriage is an important priority for parents, healthcare professionals and charities(13). The James Lind Alliance has prioritised research to develop optimal treatment and support for those experiencing psychological distress after miscarriage. New maternal mental health services, launched following publication of the NHS Implementation Plan, focus on perinatal (i.e. pregnancy loss ≥28 weeks) trauma and loss(14). Many of these services are incorporating Peer Support Workers in their skill mix. Whilst this is very welcome, not all services cover miscarriage and, for those that do, there is a real imperative to understand which interventions may be helpful.

2.1. The role of peer support in current health and social care policy

Since its introduction into community mental health services in the 1990's the concept of peer support has evolved and is now used to describe a broad range of services and activities(15). Defined as '*an equal',* a 'peer' is someone with whom one shares demographic or social similarities whereas *support* refers to *"the kind of deeply felt empathy, encouragement, and assistance that people with shared experiences can offer one another within a reciprocal relationship"(16).* Dennis (2003)(17) defines peer support as "*the provision of emotional, appraisal and informational assistance by a created social network member who possesses experiential knowledge of a specific behaviour or stressor and similar characteristics as the target population"* (p.329). Peer support relates to support, hope and encouragement provided to those in similar situations(18). A key underlying component of peer support is shared experiences; peers are better situated to establish connections of trust and support with those in need(19).

Peer support is a core component of Universal Personalised Care, which is at the heart of the NHS Long Term Plan(20). The Department of Health and Social Care (DHSC) strategy(21, 22) advocates peer support as a driver to increase community capacity and sustainable healthcare. Peer support is being increasingly adopted within both mental health services and voluntary, community, faith and social enterprise (VCFSE) organisations. There is an extensive evidence-base on the success of peer support in widening access to healthcare(23, 24). Some research has demonstrated the benefits of peer support in perinatal mental health. Reported outcomes for those receiving peer support include: improved self-efficacy(25), improved self-esteem(26), reduced social isolation(27), increased confidence(28), reduced depressive symptoms(29).

The National Centre for Miscarriage Research calls for the use of The National Bereavement Care Pathway to support parents after miscarriage. However, evidence suggests that this is not routinely undertaken, leaving parents feeling isolated and unsupported(30). This study therefore reflects the current drive in service provision for parents after miscarriage and will provide a robust evidence-base to inform future service delivery. Little is currently known about whether, and how, peer support can improve mental health outcomes for parents after miscarriage; this study will bridge this evidence gap.

3. RATIONALE FOR CURRENT STUDY

A 2012 Cochrane systematic review sought to explore the impact of psychological follow-up on the mental wellbeing of women after miscarriage. The review included only randomised controlled trials (RCTs) and produced inconclusive results(31). The review highlighted that low-quality trials were common, with a lack of standardised interventions and outcomes measures at specific time points. Another systematic review conducted in 2017 explored the effectiveness of psychological interventions in reducing stress in women after miscarriage. The adoption of a narrow focus on RCTs resulted in an "empty" systematic review whereby no studies matching the inclusion criteria were found(32). The proposed study will represent the first systematic reviews to evaluate the barriers to, facilitators of, and effectiveness of peer support interventions on improving mental health outcomes for parents after miscarriage. We will look to explore a range of study types, beyond RCTs, including quantitative, qualitative and mixed-methods research designs, as well as looking to include

unpublished evidence.

Qualitative and mixed-methods research exists exploring barriers to peer support for parents after miscarriage. Barriers identified included access problems (e.g. finding support through 'luck')(33), variability in service provision and cultural norms(34), as well as implementation issues such as time constraints and lack of resources(35). While systematic reviews exist exploring peer support for people experiencing mental ill-health, to improve their mental health outcomes(36-38), there are currently no systematic reviews exploring the effectiveness of, barriers to or, facilitators of, peer support interventions to improve mental health outcomes for parents after miscarriage. This research will address this knowledge gap. The systematic reviews within this study will adopt a broad scope. All peer support interventions that provide either emotional, informational and/or appraisal/affirmational support will be included within the search criteria, and no restrictions applied to either the study design or intervention setting.

Successful implementation of peer support interventions depends on the knowledge and understanding of specific barriers to, and facilitators of, peer support to improve mental health outcomes after miscarriage. Currently there are no systematic reviews or evidence syntheses on this topic; this study will address this evidence gap.

3.1. Why is this research needed now?

Despite the known potential psychological impacts of miscarriage, there are fewer psychological support services available after miscarriage than there are for later perinatal loss(39, 40). The study responds to the recent Pregnancy Loss Review, published in July 2023, that states "current mental health provision for individuals following pre-24-week baby loss is insufficient and must be improved to ensure support is easily accessible for anybody who needs it" (41). Miscarriage and perinatal mental health research priorities have also been identified by the James Lind Alliance and this study will contribute to a growing evidence-base to support the DHSC's strategy for sustainable healthcare(21, 22). In order to deal with current challenges and demands on healthcare services, there is need to explore new ways of working, and the most appropriate skill-mix in the workforce. At both local and national levels, peer support may be an appropriate way to manage demand, reduce inequalities, and create healthier communities(22).

Maternal mental health services were first developed in 2021 with 10 early adopter sites, followed by 22 fast follower sites. This is now extended to a national roll out in England from April 2023. It is crucial that services have clear guidance about how best to provide care after miscarriage and in particular, how best to utilise peer provision.

Given the frequency of miscarriage in the population and the associated rates of psychological distress there is call for effective and sustainable VCFSE support to meet service user need. Additionally, little attention has been paid to wider structural determinants, such as socioeconomic disadvantage and discrimination, and how these may interplay with interventional action. Earlier studies have not sought to understand how and why interventions function differently for different people in different settings, nor the negative or inadvertent consequences that can ensue. Qualitative interviews conducted as part of this study will address these gaps. The research will provide evidence on whether incorporating 'experts by experience' into maternal mental health service delivery works, and what the barriers and facilitators to this type of support may be.

This study will explore the effectiveness of, and barriers to and facilitators of, peer support interventions to improve mental health outcomes for parents after miscarriage. In line with the Public Health Research (PHR) Programme remit, our approach will generate new knowledge by not only including published work but incorporating unpublished work and primary qualitative research study with service users/providers. The

findings will strengthen the evidence-base for peer support interventions after miscarriage, underpinning recommendations for service improvement and future research priorities as well as enabling parents to make informed decisions about their participation in peer support interventions after miscarriage.

4. RESEARCH QUESTION/AIM(S)

4.1. Aim

To locate, appraise and synthesise evidence on the effectiveness of, barriers to and facilitators of peer support interventions to improve mental health outcomes for parents after miscarriage and to validate these findings through a primary qualitative research study exploring parents/provider views and experiences, and what works well for whom.

4.2. Research Question

What is the effectiveness of peer support interventions to improve mental health outcomes for parents after miscarriage and what are the barriers to, and facilitators of these interventions to the population?

4.3. Objectives

The research aim will be met through the following four research objectives through two convergent parallel work packages (WP):

(1) To systematically review evidence pertaining to the effectiveness of peer support interventions to improve mental health outcomes after miscarriage (WP1).
(2) To systematically review published and unpublished literature on barriers to and facilitators of successful implementation of peer support interventions to improve mental health outcomes after miscarriage (WP1).
(3) To conduct an overarching synthesis of (1) and (2) to integrate the findings by exploring whether the barriers and facilitators findings can help explain the effects (or lack of) of peer support interventions to improve mental health outcomes for parents after miscarriage (WP1).
(4) To conduct an in-depth qualitative study to determine multiple perspectives on the findings from the systematic reviews and to explore, with parents offered peer support after miscarriage and peer support providers, the barriers to, and facilitators of, peer support interventions (WP2).

5. THEORECTICAL FRAMEWORK

We intend to meet our objectives across two conceptually linked work packages(42). We will use Dennis'(17) conceptual analysis of peer support within a healthcare context to underpin the linked work packages. Dennis(17) describes three types of support within their definition that are common to most peer support interventions; emotional, informational and appraisal/affirmational support. Furthermore, intervention theory stresses the vital importance of context in understanding mechanisms of change; what "works" in one time and place may be ineffective, or even harmful elsewhere(42). Therefore, we will apply a pragmatic adaptation of the Template for Intervention Description and Replication (TIDieR)(43), providing a comprehensive taxonomy related to the intervention characteristics, in conjunction with Dennis' conceptual analysis of peer support, to underpin our reviews (WP1) and combine this with qualitative evidence (WP2) that pays attention to the way in which contexts of peer support provision interplay to impact outcomes(42, 43)(42, 43)(42, 43)(42, 43)(41, 42).

A logic model, based on Dennis'(17) conceptual distinctions of peer support, will be used to make explicit links between interventions, mechanisms and outcomes. The logic model will be iteratively refined throughout the study bringing together findings from WP1 and WP2 to make recommendations for the future practice of peer support after miscarriage.

6. STUDY DESIGN AND METHODS

A mixed-methods study design will be used, with a systematic review and evidence synthesis running convergently with a primary qualitative research study.

6.1. Work Package 1: Evidence Synthesis

6.1.1. Aim

To locate, appraise and synthesise the evidence on the effectiveness of, barriers to, and facilitators of peer support interventions to improve mental health outcomes for parents after miscarriage.

6.1.2. Design

Evidence synthesis methodology will be used to locate, appraise and synthesise evidence, where available, on both effectiveness, and barriers and facilitators to implementation, with input from a network of experts in the field, through a call-for-evidence. Our scoping searches indicate that peer support interventions after miscarriage have not been formally evaluated in a systematic review. Furthermore, to look only at effectiveness would ignore the complexity of how peer support interventions are viewed by those who use them. We have searched PROSPERO to confirm that there are no ongoing reviews in this area and as mentioned above, have conducted preliminary scoping searches to inform the design of this research.

We will conduct a mixed-methods evidence synthesis using a convergent segregated approach(44) to answer two review questions:

Review question 1 (R1): What is known about the effectiveness of peer support interventions to improve mental health outcomes after miscarriage?

Review question 2 (R2): What are the barriers to and facilitators of implementation of peer support interventions to improve mental health outcomes for parents after miscarriage?

R1 and R2 will be conducted in collaboration with our Public Advisory Group (PAG). We have worked with our PAG on the development of the protocol. We will continue to work with them, asking them to critique the synthesis, help us to interpret the findings and co-produce research outputs (e.g. plain language summary).

We will integrate consideration of inequalities across the evidence syntheses to highlight any unwanted effects of peer support interventions and difficulties in accessing/engaging with peer support across disadvantaged groups using the Health Inequalities Assessment Toolkit (HIAT) (1). Understanding the role of inequalities in the context of the barriers and facilitators review could help identify more equitable interventions that may be considered in service design. We will also look to include, depending on literature, a separate subsection of the review focusing specifically on those who experience multiple miscarriage.

Both reviews will be conducted in accordance with internationally recognised standards (e.g. Centre for Reviews and Dissemination (CRD) Report 4, JBI)(44, 45) and reported in accordance with appropriate review guidelines (e.g. Preferred Reporting Items for Systematic Reviews and Meta-Analyses)(46). The review protocol

will be registered with PROSPERO International Prospective Register of Systematic Reviews.

6.1.2.1. Eligibility Criteria

Population: Parent(s) (i.e. women and birthing people or their partners) with experience of miscarriage (loss of pregnancy up to 24 weeks gestation).

Interventions: Peer support interventions for parents after miscarriage. Studies will be included that assess an intervention delivered by peers or lay people to parents (women and birthing people or their partners) after miscarriage.

Peer support will be defined in this review as the existence of a community of common interest where people gather (in person or virtually by telephone or computer) to share experiences, ask questions, provide emotional support, and gain self-help. This is consonant with definitions used in published Cochrane Reviews(47, 49).

Peer support encompasses a continuum of interventions of various degrees of formality, all of which emphasise the role of personal experience in the provision of peer support. We define peers as people who are not medically trained but are like the target population because they have similar or relevant health experience(47). Peers can be people who share common characteristics with a specific individual or group, affiliating and emphasizing with and supporting each other to promote health and deal with life problems(48). We will exclude families, partners, and parents as peer supporters because they are not classified as general peers.

Interventions utilizing a formal or professional facilitator, alongside peers, will be included, provided the role of the facilitator is to manage group interpersonal processes rather than to provide counselling or any other psychoeducation.

Interventions that are both one-to-one and group based and both face-to-face and those that are technology-assisted (i.e. conducted over the telephone or internet) will be included.

Due to the heterogeneity of the interventions, we anticipate that duration and frequency of interventions will be highly variable. Interventions will be categorised by support type utilising Dennis'(17) definition of peer support; emotional, information and appraisal/affirmational support.

We will exclude studies where interventions are delivered by non-peers (i.e. interventions which may meet the criteria of a lay-led intervention but not considered to include peer support (e.g. those delivered by adult community health workers). Studies will be excluded where the primary focus is something other than developing and supporting peer networks (e.g. where professionals deliver an educative component or formal therapy) and in which improved peer networks are an incidental outcome.

Comparator: Any peer support intervention delivered to parents after miscarriage versus control (no treatment, wait list or usual care), any peer support intervention versus another psychosocial intervention, or no comparator.

Outcomes of Interest (*R1: Intervention effectiveness*): We will include studies that report any of the broad groups of outcomes below (whether validated or by self-report):

- Personal recovery – studies reporting any measure of recovery will be included. Studies reporting any outcome defined as a component of recovery by the CHIME framework will be included. This acronym refers to connectedness, such as relationships, hope, identity, meaning and empowerment. Studies reporting self-esteem, personal confidence, self-efficacy and quality of life will also be included.
- Clinical recovery – studies reporting clinical outcomes, such as any measure of psychiatric symptoms (e.g. depression, anxiety, grief, trauma), including symptom scale ratings or clinical recovery rates, and any clinical measures of social functioning.
- Health service utilisation – studies reporting any measure of uptake of other related miscarriage services or mental health services.
- Social outcomes – any additional psychosocial outcomes, such as that related to social support (e.g. measures of social network or other social support within the community, family cohesion)

Secondary outcomes may include:

- Satisfaction with the intervention (when data is available)
- Incidental learning/improved knowledge (when data is available)

Phenomena of Interest (*R2: Barriers and facilitators*): Process factors which may influence outcomes include barriers to and facilitators of uptake of peer support interventions to improve mental health outcomes for parents after miscarriage to both recipients and providers. We define a barrier as a factor that impedes the effectiveness of, involvement in, or implementation of (including economic barriers), a peer support intervention. We define a facilitator as a factor that enables the effectiveness of, involvement in, or implementation of (including economic enablers), a peer support intervention(50). Participant and provider views and experiences of peer support interventions, when data is available, will also be important to understand. Views and experiences may include, but not be limited to, preconceptions, satisfaction, concerns, anxiety and complaints.

Context: Peer support interventions that are organised and delivered in any setting (e.g. hospital, clinic, community, online). To enhance applicability to NHS healthcare settings, we will include studies undertaken in an Organisation for Economic Co-operation and Development (OCED) country.

Study Types: For R1 we will include any primary search study design with an evaluative component (e.g. any study design that reported within or between group comparative data, including studies with an independent control group, randomized controlled trials or single-group pre-intervention–post-intervention studies). For R2 we will include qualitative, quantitative and mixed-methods primary studies. Published and unpublished, completed studies will be eligible for inclusion. We will exclude conference abstracts, protocols and reviews.

6.1.3. Search Strategy

A single sensitive search strategy will inform the evidence syntheses with results filtered into the relevant reviews. The search strategy will be developed in conjunction with the review team, PAG and an experienced information specialist (MM). A search will be initially developed for MEDLINE then translated for other databases: CINAHL; APA PsycInfo, Web of Science (all databases); EMBASE; CENTRAL; ASSIA; British Nursing Index and Health Management Information Consortium. An example search strategy utilising both subject headings and free-text terms is provided in Appendix 1. Sensitivity analysis will compare the retrieval of different search techniques to optimise capability. Search strategies will be tested using a known set of relevant studies and will be peer-reviewed. All databases are available to reviewers via the University of

Liverpool Library and the NHS Knowledge and Library Hub. A targeted supplementary search using Google Scholar will also be conducted.

Reference lists of included studies will be scanned and citation searches will be conducted on included studies.

6.1.3.1. Unpublished literature

Results from the scoping searches suggest that relevant information is likely to be found in grey and unpublished literature supporting our study approach to search beyond published literature. Initial conversations with local VCFSE organisations revealed that there are unpublished materials that could be accessed through a call-for-evidence.

We will conduct a broad search for grey and unpublished literature by:

- Asking steering group members to identify topic experts, useful websites, and organisations to contact (e.g. Miscarriage Association, CRADLE, Tommy's, National Childbirth Trust)
- Scanning relevant websites for relevant literature
- Searching unpublished postgraduate theses (e.g. ProQuest Dissertations and Theses) – list of titles will be obtained and screened
- Targeting topic experts, stakeholders, and providers through a call-for-evidence(51, 52) to identify unpublished data/research in progress. The call-for-evidence will be shared through networks, direct emails, and targeted social media.

Searches will be limited to papers published since 1990 when peer support was formally introduced as a service in mental health care(15). Both UK and international studies, written in English, will be included as we believe elements of peer support provision in other healthcare/non-clinical settings may be transferable to the UK. Search results will be downloaded into EndNote and de-duplicated. Results will be screened in Rayyan(53).

6.1.4. Study selection, data extraction and quality assessment

Two reviewers (overseen by MM/GC) will independently screen titles and abstracts against the eligibility criteria to identify relevant papers for full-text review. They will then screen full texts against the eligibility criteria for final inclusion in the review. Any discrepancies in the inclusion of abstracts or full-text articles will be resolved by discussion, to reach a consensus, or by referral to a third reviewer.

Data extraction and quality assessment forms will be piloted and appropriate quality assessment tools (e.g. Cochrane Risk of Bias 2.0, CASP, Mixed Methods Appraisal Tool (MMAT(54)) will be used. Participant characteristics related to PROGRESS+(55) inequalities domains will be recorded, where reported. One reviewer will independently conduct data extraction, quality assessment and populate a pre-defined table, with a second reviewer cross-checking the data extraction and quality assessment. We will describe the following for each included study: setting, sample demographics, methodology used, description of the peer support intervention (using an appropriate template such as the Template for Intervention Description and Replication (TIDieR) Checklist(43)), range of outcomes measured and the means by which they are measured, use of theoretical frameworks, estimates of impact on recipients and providers (R1 only), a description of barriers, facilitators (R2 only) and costs of the intervention. Included study characteristics and quality assessment will be presented in tables and narratively summarised.

6.1.5. Data analysis and synthesis

For R1, we will extract quantitative data as reported and, where data allows, standardised in evidence tables

(noting any calculations). Statistical meta-analysis will be carefully considered with respect to heterogeneity of evidence. If appropriate, RevMan (for example) will be used for meta-analysis, to produce forest plots and explore heterogeneity. Forest plots may be used for single studies. Professor Richard Whittington will support the Post-Doctoral Research Associate in any meta-analysis required. RW is well versed in the strategies required to combine statistical results from two or more existing studies. In many of the areas in which he works studies may be too small to provide convincing data but has been able through meta-analysis to improve the precision of the evidence. Similarly, he has used meta-analysis to settle divergences between conflicting studies and he will employ methods previously used to support this project where required.

Where meta-analysis is not possible, quantitative data will be narratively synthesised. If sufficient data is available findings will be grouped based on gestation (i.e. miscarriage in the first or second trimester), single or recurrent miscarriage, setting, country (i.e. developed v. developing countries), in addition to equality domains. We will also look to list the range of outcome measures used across studies and how outcomes are measured.

We anticipate, from scoping searches, that there will be minimal information provided in studies about cost effectiveness of peer support interventions. We will present information about cost and benefit implications of these interventions when available and will provide a narrative synthesis of this evidence.

For R2, a convergent segregated approach to synthesis will be adopted consistent with the JBI mixed-methods guidance(56). Qualitative data will be analysed following Thomas and Harden's (57) 3-step approach for thematic synthesis; i) coding of text line by line: an iterative approach to coding will be undertaken with codes reviewed and revised as new data emerges. A single reviewer will code the data with a second reviewer checking the assigned codes. Any discrepancies will be resolved by discussion, ii) development of descriptive themes: all coded data will be reviewed for consistency and arranged into related descriptive themes, iii) development of analytical themes: we will use Dennis'(17) conceptual analysis of peer support within a healthcare context to guide the mapping and organisation of coded data into barriers to, and facilitators of, peer support interventions to improve mental health outcomes for parents after miscarriage. Following JBI guidance(56), quantitative data will be transformed into qualitative data by coding the data against the themes identified in the qualitative analysis. We will meet with our PAG and stakeholders to establish the relevance and transferability of findings to a wider audience and implications for practice.

We will conduct an overarching synthesis of R1 and R2 to compare the findings by exploring the extent to which the barriers and facilitators may explain the effects of peer support interventions to improve mental health outcomes for parents after miscarriage.

The review will look to (a) explore, summarise and assess the quality of the available evidence base for peer support interventions for parents after miscarriage; (b) provide an overview of the characteristics, nature and diversity of interventions currently available and (c) explore the evidence in terms of outcomes of interest including clinical and psychosocial mental health outcomes, and the acceptability and reported barriers and facilitators to implementation and engagement.

Findings will be used to determine key characteristics, resources, components and processes that should be included in peer support after miscarriage and generate key messages about the impacts of peer support interventions, consider implementation issues and assist with the interpretation of applicability in the UK context. Findings will be validated in WP2 through qualitative enquiry with parents offered peer support after miscarriage and peer support providers.

6.2. Work Package 2: Primary Qualitative Study

6.2.1. Aim

To determine perspectives on the findings from the systematic reviews and to explore, with parents offered peer support after miscarriage and peer support providers, the acceptability and accessibility of peer support interventions.

6.2.2. Design

An in-depth qualitative study using one-to-one interviews.

6.2.3. Sampling and recruitment

6.2.3.1. Parents

Parents (women and birthing people (n=30); partners (n=10) 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 will be recruited through relevant patient charities. Charities that work on behalf of parents who have experienced miscarriage (such as Miscarriage Association) and charities related to our sampling criteria (such as LGBTQIA+ charities) will be asked to distribute information about the study through their mailing lists and/or websites. The study will also be advertised via targeted social media and utilising the study webpage. Initial information provided will include a short explanation of the study and a link to read the detailed study participant information sheet (PIS). If interested in taking part, participants will be asked to email the study team directly to obtain further information.

The goal of sampling is to capture maximum variation in views and experiences of all those who have been offered and/or participated in peer support. We recognise that some populations, such as those from the LGBTQIA+ community, have added complexities in their experience of miscarriage that are important to recognise in our sample. This will be achieved through purposive sampling which will allow the research team to select eligible parents from different ethnicities, genders, sexual orientation, age ranges, number of miscarriages (single/multiple miscarriages) and different levels of uptake of peer support. These factors will be self-reported by potential participants through an online questionnaire which will be completed prior to the interview taking place. The questionnaire will ask participants' age, gender, sexual orientation, ethnicity, first 4 characters of their postcode (to obtain Indices of Multiple Deprivation), whether they have experienced multiple miscarriages, if they have a living child, what type of peer support they have been offered, whether they accepted or declined peer support, and how often they attended peer support.

We aim to interview approximately 40 parents (30 women and birthing people and 10 partners) to reflect the range of variables on which we will look to recruit.

6.2.3.2. Peer supporters

Peer supporters (i.e. those who deliver peer support interventions) will be identified and recruited through VCFSE organisations and NHS service providers delivering peer support after miscarriage, as well as through targeted social media and links to the study webpage. Initial information provided will include a short explanation of the study and a link to read the detailed study PIS.

We aim to recruit approximately 20 peer supporters, dependent on data saturation. Sampling will be purposive

with a spread of deliverers from across different sectors and charities and with different levels of experience. This information will be obtained through an online questionnaire which will ask basic demographic information as above and for peer supporters' role, organisation, length of time worked delivering peer support and how they deliver peer support (e.g. online, face-to-face, telephone, group). They will also be asked for their name and contact details as part of their indication of willingness to participate. This information will be used to generate unique study identifier for each participant and will be stored separately from the questionnaire and interview data (in a password protected document on University of Liverpool M:drive). Participants will be recruited until data saturation occurs.

6.2.3.3. Relating to all participants

The post-doctoral research associate (PDRA) will contact potential participants, inform them of all aspects pertaining to participation in the study and implement informed consent procedures for each participant. Individuals who do not sufficiently understand verbal explanations or written information in English, or who have special communication needs will not be included in the study. It will be explained that entry into the study is entirely voluntary and that any treatment, care or support they are receiving/intend to receive will not be affected by their decision to participate. It will also be explained that they can withdraw at any time without giving a reason for doing so. In the event of their withdrawal it will be explained that their data collected so far cannot be erased but will be anonymised to ensure and maintain their confidentiality. We will seek consent to use this data in the final analyses where appropriate.

6.2.4. Inclusion Criteria

6.2.4.1. Parents:

- Age 18 years and over
- Ability to give informed consent
- Parents (women and birthing people 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.

6.2.4.2. Peer supporters:

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

6.2.5. Exclusion criteria

6.2.5.1. Parents/Peer Supporters:

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

6.2.6. Interview Schedule

We anticipate interviews to last 60-90 minutes. Separate interview guides will be used for parents and for peer support deliverers. Interview guides will be developed with support from the PAG. Example topics may include; For parents: views of summary findings from WP1, descriptive experiences of peer support interventions received/offered, perceptions of barriers, facilitators and experiences of current peer support offers (location, frequency, delivery mode, expectations etc.), matching characteristics with peer supporters, or, if peer support

has not been taken up, reasons for declining support.
For peer supporters: views of summary findings from WP1, general perceptions of current peer support interventions on offer including, current practices, practicalities of implementation, perceptions of effectiveness and cost-effectiveness, barriers and facilitators and matching characteristics with peer support recipients. Why they engaged in this role, expectations versus experiences, impact on themselves and support options/experiences provided to them. Additionally, peer supporters might be asked about issues in assessing cost-effectiveness of peer support, best practice, and recommendations for future peer support interventions.

Each participant will be given a £20 voucher as a thank you and reimbursement for their time.

6.2.7. Analysis

Quantitative data from the questionnaire: N (%) and mean (SD) will be used for descriptive statistics.

Interviews will be audio-recorded and transcribed verbatim. Transcripts will first be read and descriptively coded by the PDRA. Approximately 20% of transcripts will be independently coded by HM, as a validity check, with discrepancies resolved through discussion and consensus agreement. A realist approach to thematic analysis will be used to define key themes(58-61). We will utilise Dennis' concept analysis framework as *a priori* codes for analysis(17), moving to develop further codes as the data is examined. A second stage analysis will involve discussion between the research team and members of the PAG to refine and develop higher-level themes(60). This will allow conclusions to be drawn about the effectiveness of peer support after miscarriage, the appropriateness of outcomes used to measure effectiveness, potential issues in measuring cost-effectiveness and acceptability and accessibility of peer support interventions after miscarriage.

6.2.8. Combining evidence from WP1 and WP2

The systematic review (WP1) will provide some of the basis for the qualitative work in WP2, by providing some evidence that will support the development of the interview guide and discussion. We will bring together the findings from the evidence synthesis conducted in WP1 and the qualitative interviews conducted in WP2 to inform the development of the logic model based on Dennis' concept analysis framework(17). By combining this evidence, we will look to make explicit links between interventions, mechanisms and outcomes and subsequently be able to make recommendations for future policy and practice for peer support after miscarriage. We will also look to utilise findings to understand how we could measure cost-effectiveness of peer support in the future.

7. STUDY SETTING

The systematic review and evidence synthesis are desk-based study activities which will take place at the University of Liverpool and/or at a remote location dependent on the researcher's hybrid working arrangements.

The qualitative study will primarily take place via online video call technology using Microsoft Teams. If required, the interviewee may request that the interview takes place face-to-face and suitable arrangements will be made for the interviewee to travel to meet the interviewer at the University of Liverpool.

8. REGULATORY ISSUES

8.1. Ethics Approval

Before the start of the study, a favourable opinion will be sought from the University of Liverpool's Research Ethics Committee (UREC) for the study protocol, informed consent forms and other relevant documents e.g. study advertisements.

The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

WP1 does not require sponsor approval, NHS REC favourable opinion nor NHS R&D permission as it does not involve NHS service users. The evidence synthesis will be conducted and reported to international standards.

WP2 involves service users; ethical approval will be sought from the University of Liverpool's Research Ethics Committee. Ethical approval processes will begin as soon as we have notification of a successful outcome. Data collection will not start until ethical approval for the project has been obtained. Preparation for protocols for ethics, participant information sheets and consent forms, and other supporting documentation for consideration during ethical review will be a priority as soon as the project starts. We will involve the Public Advisory Group (PAG) in the development of participant information sheets and consent forms to ensure relevance and clarity. All project staff involved in primary data collection, data management and analysis will be required to update relevant research ethics training as required by University of Liverpool and ensure compliance with GDPR requirements and the UK Data Protection Act 2018.

Consultation has taken place with service users with lived experience of miscarriage to ascertain that the design of the project does not place any undue burden or risk to potential participants. The PI (LB) has a strong track record of conducting qualitative research and is cognisant of ethical issues concerning work with vulnerable populations. The team has collaborative links with the Miscarriage Association and will ensure that all participants have the option of referral to support if necessary.

All participants will be informed of what will happen to their data and measures taken to ensure confidentiality, prior to providing consent. A data management plan will be drawn up. Qualitative interviews will be recorded on an encrypted audio recorder in line with University of Liverpool standard protocols. Audio files will be destroyed once transcribed. De-identified transcripts will be encrypted and stored on password protected computers provided by the University. These will be accessible only to select research team members (primarily the PI the PDRA and HM). Hard copy consent forms with personal details will be stored in a locked filing cabinet in the PI's University office.

8.2. Informed Consent

A participant information sheet (PIS) will be provided to all participants, in order to allow them to provide informed written consent before taking part. The PIS and consent form will be placed before the demographic questionnaire in postal contact route, and the link to the PIS and consent form will be placed before the demographic questionnaire link in the online contact route. Participants completing the online questionnaire will be asked to tick a box to confirm they have read the PIS and provided written informed consent before they can continue to the demographic questionnaire.

When inviting the participant to take part in the study, the PDRA will explain the details of the study, ensuring that participants have read the PIS and that the participant has sufficient time to consider their participation.

The PDRA will answer any questions that the participant has concerning study participation.

We will stress to potential participants: the confidentiality and anonymous nature of the study; the participants are entitled to refuse to participate, and to withdraw from the study at any time without giving a reason; and that this will not have implications for further support from recruiting organisations. It will also be stressed that their participation in this study does not form part of their support provided by these organisations. If, having read and understood the information sheet and had all of their questions addressed, participants feel willing and ready to participate, we will offer the opportunity to arrange an interview on a date that is convenient to them.

Written informed consent will be collected from each participant before the interview begins. A data management plan will be drawn up to outline methods for collecting and storing data, including informed consent.

If being conducted remotely, participants will be emailed a link to complete an online consent form and questionnaire which will be created using Microsoft Forms. Should a participant not complete their consent form and questionnaire before the interview date but are still willing to participate i.e. they answer the call for the interview and state willingness when asked by the interviewer, questions within the consent form and questionnaire will be read out by the interviewer and the participant will give their consent verbally with the researcher completing the forms on their behalf, noting that consent was taken verbally. This will be digitally audio-recorded, and the digital file saved separately to the interview recordings and labelled with the participants' unique ID number.

If conducted face-to-face, participants will provide written, informed consent and complete a paper version of the demographic questionnaire at the pre-arranged time of interview, before the interview commences.

One copy of the consent form will be kept by (or sent to) the participant, one will be kept by the research team. If the online consent form option is used, the Microsoft Forms consent form will be set up so that a participant automatically receives a copy of their responses. Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the study, continuing consent will be obtained using an amended consent form which will be signed by the participant.

Online questionnaires will be preceded by the PIS followed by a tick box to confirm that a consent form has previously been completed. The questionnaire will either end (if participants states that they have not completed the consent form) or will continue to the questions if consent has been obtained.

8.3. Potential risks and their management

Risk 1 Research with people who have experienced miscarriage generating distress or psychological harm:
Research with potentially vulnerable adults raises a risk that discussing previous experiences can trigger difficult memories. The informed consent process details the focus of the interviews. Although the focus of the interviews is of individuals experiences of peer support, there may be some elements of the discussion that participants find triggering. Potential participants will be advised that the study is voluntary, can be stopped at any time and that they do not have to answer any questions they don't want to. The researcher will be experienced in working with vulnerable adults and will avoid questions or end an interview if participant distress seems likely. We will also ensure that all participants are provided with information about how they can be linked to support from our collaborating organisation, the Miscarriage Association. We will provide a list of appropriate support services to

all participants and if a participant is in distress, facilitate contact with them if desired or deemed appropriate.

Risk 2 Research with peer supporters generating distress or psychological harm:
Peer supporters themselves have experienced miscarriage, and so involvement in an interview also potentially risks triggering distress based on past experiences. The degree of support that peer supporters receive through the organisation to which they are affiliated will vary and as a research team, we need to ensure their involvement in the research process does not cause additional distress beyond that which may be anticipated within their role. Potential participants will be advised that this study is voluntary, can be stopped at any time and that they do not have to answer any questions they don't want to. As above, the researcher is experienced in qualitative interviews and will curtail an interview if necessary. We will provide a list of appropriate support services to all participants and if a participant is in distress, facilitate contact with them if desired or deemed appropriate.

Risk 3 There is a risk that the research topic might lead to disclosures from the participant concerning activities that represent a threat to themselves or others:
All participants will disclose personal data. All data will be treated as confidential, except when an issue of serious potential harm to the participant, a significant other (i.e. partner, family member), or a child is concerned. To maintain confidentiality, we will ensure rigorous data management and take precautions to store data safely (see 8.4 Confidentiality and Data Protection).

We will draw up a list of support services to refer participants to, who can address any health and welfare needs that are raised during the interview. This will be done in collaboration with the Project Management Group and Public Advisory Group. During the informed consent process, the interviewer will make participants aware that we are obliged to report 1) any harm to a child, or 2) significant and immediate danger to participants themselves or others (e.g. suicidal feelings), that we become aware of during interviews. If participants report 1) harm to a child, or 2) significant and immediate danger to themselves, then the interview will be stopped. We would inform the participant of our need to contact appropriate authorities, and ideally seek their consent to do this. The interviewer would then consult with the Chief Investigator about the appropriate course of action.

Risk 4 There is a risk that co-investigators, PAG members and/or stakeholders might experience emotional distress:

The role and recruitment information for PAG members and co-investigator/stakeholder operating procedures will include a suggested procedure for emotional distress. This will include options to withdraw from or pause activities. For in-group activities/discussion, the facilitator will follow-up any stated distress, focusing on an offer of support. Signposting will be offered and if concerns are identified, the PI will be informed and a support plan, which could also include withdrawal from an adviser role or a pause, will be put in place.

8.4. Confidentiality and Data Protection

The Chief Investigator will preserve the confidentiality of participants taking part in the study and will abide by the Data Protection Act 2018 and the UK GDPR as amended from time to time and any successor legislation in the UK and any other directly applicable regulation relating to data protection and privacy.

The University processes personal data as part of its research and teaching activities in accordance with the lawful basis of 'public task', and in accordance with the University's purpose of "advancing education, learning and research for the public benefit".

Under UK data protection legislation, the University acts as the Data Controller for personal data collected as part of the University's research. The Chief Investigator acts as the Data Processor for this study, and any queries relating to the handling of personal data can be sent to Dr Leanne Burton (Email: lrburton@liverpool.ac.uk) who is the Chief Investigator for this project.

Data will be the information provided by participants and for which they have provided consent. This will include: consent forms, demographic questionnaires, and audio recordings, transcribed verbatim following each interview.

Paper-based consent forms will be personally collected by the Researcher. At the earliest opportunity all paper-based data will be scanned and stored on a University of Liverpool Managed Windows System Computer - saved under a secure drive (M: drive). All paper-data will then be confidentially destroyed once it has been saved electronically. With participants permission, interviews will be audio-recorded by the researcher using a digital audio recorder. As soon as possible after the interview has finished the audio-recording will be transferred to secure storage within the University of Liverpool computer system and deleted from the recording device.

Personal data collected from participants will be logged using a unique participant study reference number. This study reference number will provide a link to the participants' identity and will be stored securely and separately from any other study data and documents. Personal data will only be accessible to the research team to undertake quality control, audit, and analysis. There are no limits to this confidentiality.

All personal data will be anonymised to make sure that participants cannot be identified (i.e. names and personal information will be removed and replaced with a study reference number which will be unique to each participant) and treated confidentially. Anonymised quotes from individual interviews may be included in study reports, publications and/or presentations.

Participants rights to access, change or move their information is limited, in order to ensure the reliability and accuracy of the data. Participants will be able to withdraw from this study and any information collected up until completion of the data analyses phase of this study can be destroyed. After this point data will not be able to be extracted from the data analyses but will be anonymised to maintain participant confidentiality.

At the end of this study, all personal data, stored separately and confidentially as electronic files within the University of Liverpool computer system, will be archived within the University of Liverpool's Active Data Store (ADS). Data will be confidentially destroyed once the period of time needed to verify and defend, when required, the study process and outcomes has elapsed, which will be 10 years.

8.5. Indemnity

The University of Liverpool holds Indemnity and insurance cover with Newline Insurance Company, which apply to this study.

8.6. Audits

The study may be subject to inspection and audit by the University of Liverpool under their remit as Sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Framework for Health and Social Care Research (v3.2 10th October 2017).

8.7. Study Management

Dr Burton will meet with the research team (PDRA and RA) weekly to oversee the day-to-day study management. The Project Management Group (all study co-applicants) will meet monthly. The Study Steering and Data Monitoring and Ethics Committee's with meet annually in accordance with NIHR requirements.

9. END OF STUDY

The end of the study will be declared once all data analysis has been completed, after which time only write up and dissemination activities will be undertaken.

10. ARCHIVING

At the end of this study, personal data, stored separately and confidentially as electronic files within the University of Liverpool computer system, will be archived within the University of Liverpool's Active Data Store (ADS). Data will be confidentially destroyed once the period of time needed to verify and defend, when required, the study process and outcomes has elapsed, which will be 10 years.

11. DISSEMINATION POLICY

11.1. Dissemination policy

Under UK data protection legislation, the University acts as the Data Controller for personal data collected as part of the University's research. The Chief Investigator acts as the Data Processor for this study, and any queries relating to the handling of personal data can be sent to Dr Leanne Burton (Email: lrburton@liverpool.ac.uk) who is the Chief Investigator for this project.

All public facing dissemination materials and publications relating to this study will include the following formal acknowledgement of the funders: that 'This study is funded by NIHR [Public Health Research (PHR) Programme (grant number: NIHR156802)].

Findings from this study will be summarized in a Final Study Report, a copy of which will be shared and disseminated with: the funders; all project team and steering group member organisations; members of the Public Advisory Group; qualitative study participants (as requested within the participant consent forms); and via the study webpage; and public facing dissemination events, (co-designed with the Public Advisory Group). Public facing dissemination materials to be co-designed with anticipated outputs to include: video, presentations and informatics about the study findings. Again, these dissemination materials will be made publicly available via: the study webpage and all project team and steering group member organisations.

A publication schedule will be discussed and agreed upon between project team members, with the Chief

Investigator retaining the final decision in the list of academic publications and authorship listing for each, once the data analysis has been completed.

Given the sensitive nature of the data and the small sample size, the anonymised participant level dataset will not be made publicly available following the study.

11.2. Reporting, Outputs and Ongoing Dissemination

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. Safeguarding procedures as identified within the PPI section will be followed during discussions within this event.

11.2.1. How will you inform and engage patients/service users, carers, NHS, social care organisations and the wider population about your work?

A study webpage will be created. This will provide progress updates, advertise opportunities to participate, and act as a repository for project reports and newsletters. We will utilise our links with VCFSE organisations such as the Miscarriage Association (co-applicant) and organisations we have engaged with in WP1 to provide support and advice regarding dissemination strategies and links to our webpage. National and international conferences will be attended to disseminate the research and any additional opportunities to disseminate both locally and nationally will be sought. Through our networks we will distribute findings to participants, policy makers, advisory groups, professional bodies and patient support groups. We will use a targeted social media approach to share information about the study and will make use of the university communications department to disseminate the results widely. We will seek advice from our EDI Lead (SH) on best methods to reach diverse populations. This will augment the advice from co-applicants and PAG members who represent diverse communities.

11.2.2. How will your outputs enter our health and care system or society as a whole?

Distribute dissemination materials through individuals, organisations and professional groups outlined in previous question. In addition, we will cascade our outputs through our established networks to ensure policy makers, advisory groups, professional bodies, and the wider VCFSE sector have access to findings and practical recommendations. Study collaborators (i.e. Miscarriage Association) and co-applicants (PS and RC) will provide advice and support on how to share findings, impact policy and implement in practice.

While qualitative findings will be UK centric, findings from the review will offer evidence of barriers and facilitators more broadly allowing consideration of convergence/divergence beyond the UK.

11.2.3. What are the possible barriers for further research, development, adoption and implementation?

If peer support is proven to be effective there may be an increase in demand for peer support interventions after miscarriage in the short-term which may not be met by the current peer support provision.

11.2.4. What do you think the impact of your research will be and for whom?

Improved awareness of potential consequences of miscarriage: Evidence from this study will allow identification of interventions to improve mental health outcomes that are effective, acceptable and accessible for parents who have experienced miscarriage. In line with the recently published Pregnancy Loss Review, the study will underscore a 'call to action' to develop and implement interventions to support parents. It will also provide a detailed understanding of the role of the peer-supported and inform a role description and training/support guides for NHS/VCFSE organisations to implement and share with the public.
Improved knowledge base: Evidence from this study will provide robust and valid evidence on the effectiveness of peer support interventions for people experiencing miscarriage to fill the current knowledge gap. It will provide evidence of barriers to and facilitators of peer support in practice. It will provide evidence to further understanding about the role of peer support for people after miscarriage and how this might help to address health inequalities. It will help to inform the public about the benefits of peer support for those experiencing miscarriage and to understand where they may go/signpost individuals to peer support. Finally, it will work

towards understanding how to construct cost-effectiveness within future studies of peer support interventions.
Improved policymaking: National policymakers will be provided with clear evidence of impact and identification of barriers and facilitators to peer support interventions which will allow parents to make informed decisions about the use of peer support after miscarriage, ensuring maximum benefit for service users.
Improved peer support interventions: having good practice recommendations for peer support will enable organisations to utilise known components of effective peer support interventions to make decisions about delivery and work towards facilitating standardisation of peer support. The findings from this study will inform future guidance produced by NHS England and NICE providing evidence of good practice in the development of effective peer support interventions.

11.2.5. How will you share with study participants the progress and findings of your research?

We will keep participants informed about the study's progress with regular newsletters and updates via the study's webpage and social media. We will distribute a written summary of study results to all participants. We will also organise an online dissemination webinar, which will be used to celebrate the study, thank participants for their contribution and to discuss findings.

11.3. Authorship eligibility guidelines and any intended use of professional writers

Authorship on the final study report will be open to all project team and the Public Advisory Group members.

Authorship criteria will adhere to the Authorship recommendations by The International Committee of Medical Journal Editors (ICMJE)[37] which stipulates that authors must meet each of the following criteria:

1. Have made a substantial contribution to the study design, data analysis and interpretation
2. Have either drafted the manuscript or provided critical revisions to ensure important intellectual content
3. Provide approval of the final manuscript version for publication submission publication, and
4. Provide their agreement to be accountable for all aspects of the work conducted to ensure and defend its accuracy and integrity.

In addition, all named authors must be accountable for their contributions and have knowledge and confidence in the integrity of contributions from their co-authors.

The contributions of others, who do not meet the aforementioned criteria will be acknowledged.

12. PROJECT/RESEARCH TIMETABLE

Month	Activity
Pre-Award	Recruitment of Research Assistant
1 (May 2024)	Project set up, Protocol development, Ethics application for WP2, Recruit to Public Advisory Group (PAG) Project Management Group meeting (set-up) 1/24
2 (Jun 2024)	Project set up, Protocol development, Ethics application, Recruit to PAG

	Develop systematic review search terms and inclusion criteria in collaboration with PAG Project Management Group meeting (update progress) 2/24 Stakeholder Group meeting 1/8 Public Advisory Group meeting 1/8
3 (Jul 2024)	Project set up, Protocol development, Ethics application, Set up PAG Agree systematic review search terms and inclusion criteria Register review protocol on PROSPERO Develop and test initial search strategies – conduct searches Initiate call-for-evidence Project Management Group meeting (update progress) 3/24
4 (Aug 2024)	Study selection and retrieval Supplementary materials requests Ongoing call-for-evidence Project Management Group meeting (focus on search results) 4/24
5 (Sep 2024)	Study selection and retrieval Supplementary materials requests Ongoing call-for-evidence Project Management Group meeting (focus on final study selection) 5/24 Stakeholder Group meeting 2/8 Public Advisory Group meeting 2/8
6 (Oct 2024)	Ongoing supplementary materials requests Finalise studies for inclusion Data extraction and quality assessment, TIDieR framework Project Management Group meeting (focus on final study selection) 6/24
7 (Nov 2024)	Ongoing supplementary materials requests Data extraction and quality assessment, TIDieR framework Project Management Group meeting (focus on study selection) 7/24
8 (Dec 2024)	Ongoing supplementary materials requests Data extraction and quality assessment, TIDieR framework Draft interim report for NIHR Project Management Group meeting (focus on synthesis of data) 8/24 Stakeholder Group meeting 3/8 Public Advisory Group meeting 3/8
9 (Jan 2025)	Data synthesis and analysis within each strand Begin recruitment to qualitative interviews Project Management Group meeting (focus on SR analysis) 9/24
10 (Feb 2025)	Data synthesis and analysis within each strand Qualitative interview recruitment Interim report writing Project Management Group meeting (focus on SR analysis, update on qualitative recruitment, review interim report) 10/24
11 (Mar 2025)	Data synthesis and analysis within each strand Qualitative interview recruitment

	Interim report writing Project Management Group meeting (focus on synthesis and analysis, update on qualitative recruitment, review interim report) 11/24 Stakeholder Group meeting 4/8 Public Advisory Group meeting 4/8
12 (Apr 2025)	Data synthesis and analysis within each strand Write-up of systematic review papers Submit interim report to NIHR Qualitative interview recruitment Project Management Group meeting (update on SR progress, qualitative recruitment) 12/24
13 (May 2025)	Qualitative data collection Project Management Group Meeting (review paper drafts, update on qualitative WP2) 13/24
14 (Jun 2025)	Qualitative data collection/analysis Project Management Group meeting (review academic papers, update on qualitative WP2) 14/24 Stakeholder Group meeting 5/8 Public Advisory Group meeting 5/8
15 (Jul 2025)	Qualitative data collection/analysis Project Management Group meeting (reviewing academic papers, update on WP2) 15/24
16 (Aug 2025)	Qualitative data collection/analysis Project Management Group meeting (update on qualitative data analysis) 16/24
17 (Sep 2025)	Qualitative data collection/analysis Project Management Group meeting (update on qualitative data analysis) 17/24 Stakeholder Group meeting 6/8 Public Advisory Group meeting 6/8
18 (Oct 2025)	Qualitative data collection/analysis Project Management Group meeting (update on qualitative interviews and data analysis, planning dissemination activities) 18/24
19 (Nov 2025)	Qualitative data analysis Drafting final report Project Management Group meeting (update on qualitative interviews and data analysis, planning dissemination activities) 19/24
20 (Dec 2025)	Qualitative data analysis Begin dissemination activities Drafting final report/qualitative paper Project Management Group meeting (update on qualitative data analysis, dissemination activities) 20/24 Stakeholder Group meeting 7/8 Public Advisory Group meeting 7/8
21 (Jan 2026)	Qualitative data analysis

	Drafting final report/qualitative paper Project Management Group meeting (update on qualitative data analysis, dissemination activities, report draft) 21/24
22 (Feb 2026)	Circulate draft report Writing qualitative paper Project Management Group meeting (review report, update on dissemination activities) 22/24
23 (Mar 2026)	Report feedback from stakeholders/PAG Project Management Group meeting (review report, update on dissemination activities) 23/24 Stakeholder Group meeting 8/8 Public Advisory Group meeting 8/8
24 (Apr 2026)	Submission of report, preparation of publications. Dissemination webinar Project Management Group meeting (final review meeting) 24/24

13. PROJECT MANAGEMENT

The Principal Investigator (PI) will act as project manager to oversee and co-ordinate the project start-up, recruitment and data collection, and to ensure project governance for the research. From our collective research experience, it is important that the PI has oversight of all of the elements of the work packages for quality and delivery purposes. The PI will liaise regularly with co-investigators, Public Advisors and stakeholders to ensure clear lines of communication.

A post-doctoral research associate (PDRA) will be employed (FTE=1.0 for 24 months) to undertake recruitment activities, including systematic review activities and qualitative interviews and analysis. They will be supervised by the MM/GC (WP1) and HM (WP2). The PDRA will be based at University of Liverpool. Research staff will benefit from the research infrastructure and capacity building opportunities within the University of Liverpool.

We will set up an expert Study Steering Committee (SSC) to provide independent scrutiny and advice. Meetings will be held quarterly to provide overall supervision of the study. The SSC includes a clinician, Research Midwife, Bereavement Midwife, Consultant Obstetrician, a policy expert, expert academics from within the field, and a public representative from the PAG. The SSC will consider study progress and adherence to the protocol, as well as providing advice to the PMG.

13.1. Diversity

We will ensure diverse representation in PPI and purposively sample for diversity in the qualitative components of the study. We have a strong track record within the research team of engaging diverse and marginal groups as both research participants and collaborators. SH has extensive experience through her role as PPIE lead for ARC NWC. The Public Advisor, with the support of co-applicants SH, LB, HM and GC, will bring together a diverse group of active community members in a Parent Advisory Group (PAG). Through their involvement we will look to reach into different community groups that the PAG are connected to. We will share our study opportunity more specifically with local charities/groups (e.g. https://www.acacia.org.uk/bame/mums-dads/) including the LGBTQIA+ community.

13.2. Project/research expertise

The research team has a wide range of experience and skills relevant to the study. We have maternal health expertise (Slade, Rankin, Kelleher, Bambang), expertise in evidence synthesis (Slade, Maden, Hill, Cherry), mental health research (Burton, Perkins, Mulholland, Corcoran, Cherry), health economics (Boland), health policy and commissioning (Corcoran, Perkins), health inequalities (Burton, Hassan, Maden), and PPIE (Burton, Hassan, Hill).

Lead applicant Dr Leanne Burton (LB) (25% FTE) is an early career researcher with specific interest in mental health research. LB has experience in using innovative approaches in qualitative research to reach under-served populations. LB has had two successful grant applications as PI; one evaluating a mental health and physical activity e-learning course (completed), and the other exploring ways to engage children and young people with learning disabilities and their parents/carers in inclusive research (completed), as well as co-investigator and supervisory roles in other projects including a feasibility trial evaluating a self-harm intervention in local secondary schools (ongoing).LB will lead the project with mentorship support from Professor Elizabeth Perkins (EP) and Professor Pauline Slade (PS). LB will be responsible for the governance and management of the project. LB will be responsible for the development of project materials and documents, support data analysis, induction/training for PPI in this project, write-up of final reports and papers for peer-reviewed journals.

Joint Lead applicant: EP (5% FTE) has expertise in leading research projects in the field of mental health, particularly in undertaking qualitative studies and leads the Applied Research, Innovation and Service Evaluation (ARISE) Research Group; a collaboration between the University of Liverpool and Mersey Care NHS Foundation Trust.

LB will be provided expert guidance and mentoring from EP and PS. LB and EP are co-located and will formally discuss study progress on a weekly basis. PS will attend regular monthly meetings with EP and LB to identify any issues that have arisen as well as provide informal access as needed. PS is a very experienced clinical researcher who has been awarded 33 externally funded grants covering a range of research designs from randomised controlled trials, observational studies, systematic reviews and qualitative studies. EP is a highly experienced researcher who has been awarded numerous externally funded grants in the field of health and social policy. Both EP and PS are senior staff at the home institution, highly experienced in supporting junior staff, who are totally committed to the success of this work and will provide guidance and support to LB throughout the project. They will also facilitate connections with other academics and service users where appropriate. The University of Liverpool has a commitment to the development of early career researchers through professional skills and training opportunities linked explicitly to the Researcher Development Framework, engagement with formal regular reviews via a PDR process, and the development of plans for a clear career pathway. The importance of supporting research staff in the Department of Primary Care and Mental Health as they develop their research careers is backed up by access to training budgets to ensure that staff are equipped to undertake their role.

13.3. Co-Applicants

Professor Pauline Slade (5% FTE): Professor in Clinical Psychology/Consultant Clinical Psychologist who will provide highly experienced guidance and mentorship to LB has been awarded 33 externally funded grants across a range of research designs from randomised controlled trials, observational studies, systematic reviews and qualitative studies. She is a specialist in perinatal mental health and is involved in ongoing work with a focus on developing effective interventions and systems to improve maternal mental health and wellbeing. She

led the team that produced the NHSE published guidance for the development of the maternal mental health services which cover all aspects of perinatal loss including miscarriage '*Supporting mental healthcare in a maternity and neonatal setting: Good practice guide and case studies" August 2021 NHSE.*
Dr Michelle Maden (5% FTE): Research Associate in Evidence Synthesis working for Liverpool Reviews and Implementation Group (LRiG) with expertise in information retrieval for systematic reviews and consideration of health inequalities in evidence synthesis and will co-lead on this aspect of the study with GC.
Dr Ruaraidh Hill: Senior lecturer in Evidence Synthesis. RH has led on all stages of evidence synthesis for HTA and contributed to over 70 NICE guidance projects. He has extensive experience in stakeholder engagement and will support LB in the development of the 'call-for-evidence' within the project.
Dr Gemma Cherry (5% FTE): Clinical Psychologist and Lecturer in Clinical Health Psychology with expertise in evidence synthesis. GC will support MM in co-leading the evidence synthesis element of this study.
Professor Rhiannon Corcoran (2% FTE): Professor of Psychology and Public Mental Health. RC's provides expertise in public health in particular, health policy and systems and will support LB & PS to translate these findings into public health policy and practice.
Dr Shaima Hassan (2% FTE): PPI research lead at ARC NWC. She will support co-ordination of PPI activities and be a dedicated point of contact and support for Public Advisors. SH also brings expertise in equality, diversity and inclusion, through her work with ARC NWC Seldom Heard Group, and will lead on this aspect of the study.
Dr Angela Boland (5% FTE): Associate Director of LRiG. AB works in health data science and has worked on numerous cost effectiveness systematic reviews, as well as on Single Technology Appraisals for NICE.
Helen Mulholland (5% FTE) has extensive experience of working on mental health research projects, with a particular focus on suicide and self-harm. Working as part of the ARISE Research Group, HM will provide expertise in mental health outcomes and will use her knowledge and experience to supervise WP2.
Ruth Bender Atik (fees paid at INVOLVE recommended rates): As National Director of Miscarriage Association, RBA has expertise in the delivery of peer support services. A formal letter of support is included within the application.
Sarah Little (hourly fee paid at INVOLVE recommended rates): Public Advisor to co-chair Public Advisory Group (PAG) meetings, support by providing an alternative, first-hand perspective on miscarriage, development of materials for PAG, support write-up of final reports and peer-reviewed papers.

13.4. Collaborating organisations and individuals

Liverpool Women's NHS Foundation Trust have committed to providing support to the project with expertise provided by a Research Midwife (Sian Rogers), Bereavement Midwife (Marie Kelleher) and Consultant Gynaecologist (Dr Katarina Bambang). Their knowledge of service provision within the NHS, as well as signposting to external VCFSE organisations and services will add expertise to the wider research team as part of the SSC.

In addition, Professor Judith Rankin from University of Newcastle will provide additional expertise in the field of perinatal mental health with specific research interest in reproductive loss. JR's expertise and collaborative links with a number of parent organisations will be useful in recruiting potential participants to WP2.

Professor Richard Whittington is an honorary senior research fellow in ARISE (University of Liverpool) and Senior Research Adviser at the Center for Research and Education in Forensic Psychiatry at St. Olav's Hospital, Trondheim, and a Professor at the Norwegian University of Science and Technology (NTNU). He is a forensic psychologist and a researcher with a focus on the social psychology of coercion minimization and violence prevention in mental health services. Richard has co-authored and co-edited a large number of publications on these topics over the past 25 years. He specialises in systematic reviews and meta-analysis. RW will provide statistical support in-kind and will support the meta-analysis as required.

14. SUCCESS CRITERIA AND BARRIERS TO PROPOSED WORK

Project activities: We will monitor our progress against a set of activity indicators which will reflect the activities as defined in the planned timelines indicated above. Our criteria for success will be the completion of each activity in accordance with the project timeline. For dissemination activities we will endeavour to ensure that we are impactful by: publishing in high-impact journals, nurturing our social media presence, leveraging our collective experience of adult learning and teaching to inform training, and committing to best practice when engaging with PPI. Our success criteria will reflect our performance against these ambitions.
Grant management: University of Liverpool is committed to transparent, accountable, and responsible grant management. Additional success criteria relate to adherence to the terms and conditions of the funding award, timely reporting, minimal environmental impact and responsible budget management.

Key overall project risks and mitigating procedures include:

- Delivering the project outputs on time. Potential challenges could include identification of a greater volume of studies than anticipated, or studies with considerable complexity which require additional input to appraise. Researcher absence/retention is considered low risk as there is a wide research team with overlapping expertise. Timelines, and potential risks, will be discussed at regular meetings, and mitigating actions (e.g. movement of researchers between tasks) agreed if there is a risk to project timelines.
- To ensure formation of a suitably diverse PAG (n=8), including representatives with varied social, economic and political views and experiences, we will implement plans to recruit sufficient numbers to our PAG, and a broad range, to deal with any attrition. If necessary, we will recruit additional PAG members during the project.
- To mitigate against known barriers to the active involvement of stakeholders in research, we will follow INVOLVE guidance(62). In particular, we will strive to create an environment that is inclusive, recognises the contribution of all participants, and in which people work together to achieve a shared understanding. Our strategies will be based on known good practice of PPI, including careful planning, clear communication, creation and agreement to a Terms of Reference for PAG members, provision of training and appropriate reimbursement.
- To mitigate against recruitment risks (low recruitment rates) in WP2 we will use a variety of recruitment methods, through social media outlets, and through service users at charitable organisations, as well as through our study webpage. PS is a lead co-investigator for an NIHR study evaluating the implementation of the Maternal Mental Health Services and if needed can facilitate access to services linked into peer support programmes to assist recruitment. We have costed reimbursement to thank interview participants for their time. To support inclusivity, we can offer to interview participants over the telephone or via Teams, depending on preference, and to support retention. A study newsletter will be provided to participants to help emphasise the importance of the study and help participants to feel a valued part of the research.

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