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Men living through multiple miscarriages: protocol for a qualitative exploration of experiences and support requirements

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Abstract

Introduction

Up to 1 in 4 pregnancies and 1 in 20 subsequent pregnancies end in miscarriage. Despite such prevalence the psychosocial effects are often unrecognised and unsupported. In the absence of any biomedical sequelae among men such marginalisation may be intensified. Men living through multiple miscarriages may also find any grief or anxiety intensified by loss of hope for future parenthood, but robust qualitative studies of these experiences are limited. We aim to rectify the deficiency.

Associated Data

Methods and analysis

Our qualitative study will adopt the sounds of silence framework designed by Serrant-Green to hear the voices of populations possibly marginalised. We will listen and learn from 30 to 50 men with a history of two or more miscarriages. The research participants will be recruited from a recurrent miscarriage clinic at a large tertiary hospital in England, and from advertisements to be disseminated by the project sponsor and miscarriage charities.

Individual telephone interviews supported by a semistructured discussion guide will be audio-recorded, transcribed and anonymised. The transcriptions and any field notes will be interpreted by the framework method of Ritchie and Lewis embedded within the sounds of silence framework. Tentative findings will be presented to research participants in face-to-face focus group discussion, to enable member synthesis to enhance authenticity. The focus group discussion will be audio-recorded, transcribed, anonymised and similarly interpreted to contribute to our final synthesis.

Ethics and dissemination

The protocol of this project received a favourable opinion from the West Midlands South Birmingham Research Ethics Committee (16/WM/0423). Results will be submitted for publication in peer-reviewed journals and at conferences, and disseminated via newsletters and social media of our clinical collaborators and miscarriage charities. Outputs are anticipated to inform future policy and practice in the management of multiple miscarriages.

Trial registration number

ISRCTN 21828561.

Keywords: gynaecology, public health, qualitative research

Strengths and limitations of this study.

- Our adoption of a qualitative approach is anticipated to enrich our insight to experiences unexplored to date.
- The sounds of silence framework embedded within our qualitative study design will enable voices previously silent or unheard to be acknowledged.
- Recent studies refute traditional criticisms of telephone communication to establish empathy: our individual interviews are expected to provide participants with a safe space to disclose previously marginalised experiences.

- Member synthesis will optimise the authenticity of our findings: to inform policy and practice in the supply of support for men living through multiple miscarriages.
- Participants will be recruited from a single clinical study site and advertisements to be disseminated by miscarriage charities, so the study data may be insufficient to faithfully represent the experiences of those not in receipt of support from these or comparable services.

Introduction

Miscarriage, the loss of pregnancy before survival outside the womb becomes possible at around 24 weeks of gestation, is prevalent.[1] Many cases go unreported but there is evidence to suggest that more than 200 000 pregnancies end in miscarriage every year in the UK.[2] Moreover, as many as 1 in 20 couples experience more than a single case.[3]

Most miscarriages occur during the first trimester[4] before there is any visible sign of pregnancy and possibly before pregnancy is perceptible by gynaecological ultrasound.[5] Consequently many of these early miscarriages remain unknown and unrecognised. In other cases, they remain unspoken or silenced to prevent embarrassment and stigma[6–10] engendered by an outcome that is unplanned and frequently unexplained,[11 12] or because intimate body functions and messy biological symptoms[13] are taboo.[14] As a result, the psychosocial effects often remain unacknowledged and unsupported.8–10 15–26 Marginalisation may be more acutely experienced by men because the biological sequelae of miscarriages are confined to women, and because men often find themselves cast into gender roles characterised by emotional detachment and rationality.[22 26] Yet miscarriages22 24 26–30 or other perinatal loss events[31–37] may bring disorientation, anxiety and other difficult feelings to either or both partners. Some of these emotions and uncertainties may be intensified by recurrence: those who encounter repeated miscarriages may be affected by fear of chronic pathology and loss of hope for any healthy pregnancy in the future.[38–45]

The National Bereavement Care Pathway[46] underpins ongoing improvements in professional capability and practice to offer psychosocial support, but resources are limited and perhaps not accessible to everybody.[25 47–50] Interventions and services may be prioritised towards later miscarriages or stillbirths accommodated in obstetric facilities not early pregnancy units,[29 47] or towards only women as the rightful recipients of care.[22 26 51] Some clinicians also describe inadequate time or instruction to bear the burden of any emotional labour.16 23 25 52 Consequently it is unsurprising that many individuals and families report inadequate information and emotional support to navigate early miscarriages.[15 17 22 23 25 26] They also advocate more research to better understand the psychosocial consequences.[53]

Most previous studies adopt quantitative measurements of distress among women.[38–41 43 45] There are fewer qualitative studies,[54] and even fewer to focus on experiences among men.[22 26] Moreover, the effects of miscarriages are often conflated with the effects of other perinatal loss events.[31 32 35 55] We recently published a systematic review and thematic synthesis of 22 qualitative studies with any male participants who had lived through one or more miscarriages. We were unable to identify any previous research dedicated to examine the effects of more than a single loss before 24 weeks of gestation among men.[26] The European Society of Human Reproduction and Embryology has observed the gap in the evidence and in November 2017 explicitly recommended investigative action to remedy it.[56] This manuscript presents the protocol of an empirical study designed to explore male experiences and support requirements with a qualitative approach.

The men living through multiple miscarriages study

Aims and objectives

We aim to explore the experiences of men who have lived through multiple miscarriages, in order to inform the design and delivery of interventions intended to support them. We refer to experiences to include thoughts, emotions, uncertainties, interactions, expectations and/or preferences among the sample population.

Our research objectives are:

- To explore any thoughts, emotions and uncertainties engendered by multiple miscarriages.
- To explore experiences of interactions with partner/s during and after these miscarriages.
- To explore experiences of interactions with family, friends and colleagues.
- To explore any expectations of future parenthood.
- To explore any expectations and/or preferences in miscarriage support (to include professional support).
- To explore opportunities and ideas to meet any support requirements.
- To apply these explorations to inform recommendations for policy and practice in the management of multiple miscarriages.

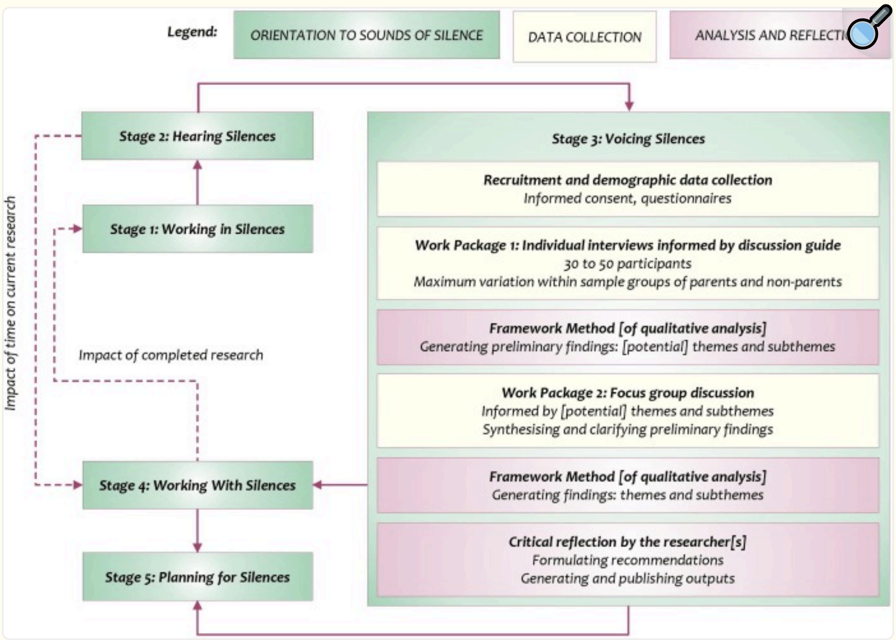
Methods and analysis

Theoretical orientation and study design

Our theoretical orientation is underpinned by a recognition that lived experiences are socially constructed[14 57–59] and mediated by uneven power relations between different people.[60 61] Foucault demonstrated connections between power and knowledge, and observed multiple silences amid the multiple sayings of discursive reality: he also coined the concept of biopower to describe interdependency between biological being and social identity.[62–64] More recently, Hazen,[6] Martel[55] and other theorists[7 8] described how miscarriages are swathed in silences, and appealed for more disclosure to overcome objectification and biomedical control of the pregnant-unborn body. However, these commentaries on the socially situated experiences of miscarriages maintain a focus on death before birth as a female issue: we hope for our study to widen the discussion to include men.

Serrant-Green[65] identified sounds of silence[65 66] in beliefs and behaviours that are neglected or little understood by dominant social discourse or academic research. She devised five stages of action to bring them into public earshot and knowledge. Our project illustrated in figure 1 is similarly designed to facilitate awareness of ideas important to our study participants and possibly previously unspoken or silenced. The study is configured to collect and interpret data with a qualitative approach, to hear the voices and to construe the meanings communicated by the sample population more freely and deeply than could be hoped via quantitative measurement.[67–70]

Figure 1.



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Data collection and analysis embedded within the sounds of silence framework.[65 66]

In order to overcome the difficulties associated with recruitment among possibly marginalised[71] populations we consulted a patient and public advisory panel to optimise our enrolment strategy. Recruitment commenced in September 2019 and we expect to complete data collection and analysis during 2021.

Participants

Table 1 lists our inclusion criteria broad enough to facilitate ethnic and socioeconomic diversity, alongside exclusions to ensure the collected data represent contemporary experiences of miscarriages and miscarriage care.[72] We seek to recruit men who have lived through two or more pregnancies that were clinically confirmed but then ended spontaneously before 16 completed weeks of gestation. The gestational threshold of our research interest is guided by likelihood for later miscarriages to be diverted away from early pregnancy units towards obstetric facilities.[50] Eligibility will be limited to men with the most recent loss no more than 12 months ago to facilitate recall, and without any infertility diagnosis to eliminate possible confusion with experiences of other reproductive challenges.

Table 1.

Inclusion and exclusion criteria

Eligibility	Criteria
Inclusion	Male AND Aged 18 years or more AND Experience of two or more clinically confirmed pregnancies that both ended spontaneously before 16 completed weeks of gestation AND Able to hold a conversation in English AND Able and willing to give informed consent to participate in audio-recorded telephone interview
Exclusion	More than 12 months since most recent miscarriage OR Infertility diagnosis

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Our previous research[26] and consultations with members of the target population suggest that psychosocial responses to miscarriages may be influenced by perceptions of parenthood.[26] Therefore, we will recruit purposively[73] to achieve maximum demographic variation among men who identify themselves as parents and those who do not. On the basis of experience gained in comparable studies, we anticipate that between 30 and 50 participants will be enrolled. However, recruitment, data collection and analysis will continue until we achieve analytic saturation with rich and comprehensive insight to satisfy our research objectives.[74 75]

Recruitment

Men will be invited to participate in the study by healthcare practitioners located at the recurrent miscarriage clinic of a large tertiary National Health Service (NHS) hospital in England, and by advertisements to be disseminated by local and national miscarriage charities and peer support forums.

Within the clinical setting, prospective participants will be identified and approached in the first instance by an appropriately trained member of the usual care team. The doctor, nurse or midwife will offer a leaflet with information about the study, and either signpost eligible and interested individuals to contact the research team directly, or take written consent for the research team to initiate direct contact.

Outside the clinical setting, information about the study and contact details of the research team will be available from a webpage dedicated to the project, to be advertised via newsletters, tweets and other social media of the study sponsor and charitable organisations active in miscarriage research and support. The webpage may also be signposted by those already recruited. We recognise possibilities for chain referral to result in a narrow demographic range, so we aim for broad dissemination through charitable partners to forestall dependency on a snowball effect.[71]

Informed consent

Subsequent to introductions and expressions of interest, the research team will liaise with prospective participants by email, telephone and/or short message service (SMS) to ascertain eligibility and to enable informed consent prior to any data collection. All those invited to contribute to the study will be encouraged to consider the decision carefully. It will be made clear that participation is entirely voluntary, with freedom to withdraw at any time until the contributed material is anonymised and assimilated to the data corpus.

Informed consent will include agreement to supply brief demographic details, in addition to audio-recorded telephone interview within our work package 1 described below, and anonymised data release. Demographic information will enable us to achieve maximum variation among the study sample. At the time of informed consent we will additionally describe the opportunity for participants to join a focus group discussion about preliminary findings within our work package 2. However, contributions to the focus group discussion will remain entirely optional.

We will make every effort to secure written records of informed consent with wet signatures, but a flexible approach may be necessary in the absence of face-to-face interactions.[76–79] Table 2 describes our preparations to facilitate recruitment without undue loss of fidelity to ethical principles of voluntary participation, research integrity and transparency.[79 80]

Table 2.

Methods of informed consent

Issue of Information	Completion of Consent Form	Return of Consent Form
In advance of interview		
Postal delivery	Fill and sign in wet ink by hand	Pre-paid postal delivery OR Scan and email as attachment/s OR Photograph and email as attachment/s
Email with attachment/s	Print, fill and sign in wet ink by hand OR Complete, sign and save electronically	Pre-paid postal delivery OR Scan and email as attachment/s OR Photograph and email as attachment/s
Secure online survey interface[116]	Complete and sign online	Submit online
At the beginning of audio-recorded interview if methods above are unfeasible		
Read out line-by-line	Respond verbally to each item	Not applicable

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Data collection in work package 1: individual interviews

The study team will liaise with each prospective and consented participant by email, telephone, SMS and/or post to arrange a mutually convenient opportunity for semistructured interview via telephone within our work package 1. Semistructured interactions will enable informants to tell us their stories[81] freely enough to yield rich textual data, but without undue diversion to issues beyond the scope of our study objectives.[74] Semistructured dialogue will also enable investigators to compare different stories more easily than unstructured discussions.[74 82] Interpersonal rapport is essential to an effective qualitative interview, and recent studies refute the historical criticism that it is difficult to establish empathy[83 84] via telephone. There is now evidence to suggest that telephone communication may facilitate a sense of anonymity, privacy and freedom, and thereby confer more relational power to interviewees.[85–89] Telephone interviews also offer logistic convenience and feasibility to extend the geographical range of the study population,[85–88 90 91] and they reduce any personal safety risks.[85 87]

Our interviews are anticipated to last up to 60 minutes each. Ongoing consent will be verified and then a semistructured discussion guide will support a purposeful conversation with appropriate prompts if required.[92] The interviewer will seek to explore experiences and support requirements considered to be important by the interviewee. The discussion guide may be iteratively refined during the period of data collection to enrich data capture, but indicative contents are illustrated in figure 2.

Figure 2.

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Indicative contents of semistructured interviews.

All audio-recordings will be transcribed verbatim by specialist transcription suppliers subject to confidentiality agreements to prevent disclosure to third parties. The study team will review each transcription to ensure accuracy and to anonymise any personally identifiable data. Then the textual contents will be interpreted and preliminary findings will be presented to study participants for member synthesis within our work package 2.

Data collection in work package 2: focus group discussion

Different voices and silences are audible to different people,[65 66] so within our work package 2 we will undertake member synthesis,[65 66 93 94] to enable study participants to elaborate or reconstruct our preliminary interpretations of interview data.[93–95] We will facilitate face-to-face focus group discussion at an accessible location in central England to explore whether or not stories heard and reported by researchers resonate with perceptions among the sample population. We anticipate collective dialogue to elucidate similarities and differences between individual experiences, with additional opportunities to learn from discursive interactions among the members.[96–101]

Invitations will be issued to all study participants by email, telephone, SMS and/or post. Contributions will remain entirely voluntary and ongoing consent will be verified verbally on the day. After consent is confirmed our preliminary findings in the form of tentative themes and descriptive or explanatory conclusions will be presented for confirmation or refutation with new insights and interpretations. Members will be invited to reflect and comment, and to consider any implications for further research or other action.

Focus group discussion is expected to last for up to 120 minutes, supported by a semistructured guide if required to encourage constructive contributions from everybody.[96 97 102 103] The event will be audio-recorded, transcribed verbatim and anonymised for further analysis and assimilation to our final study results.

Data collection in work packages 1 and 2: honoraria and expenses

All men recruited to the study will be entitled to receive a small honorarium in recognition of the time and effort incurred in interview participation, and a further honorarium for contribution to focus group discussion. Each of these honoraria will take the form of a £20 digital high street voucher to be issued after data collection. Participants in the focus group discussion will also be entitled to reclaim reasonable travel expenses.

Data analysis

Study data collected in interviews and focus group discussion will be examined and interpreted via the framework method established by Ritchie and Lewis[104] and further described by Gale *et al*.[105] The framework method is sufficiently flexible to suit different theoretical positions and adaptable to inductive or deductive analyses.[105 106] It is also anticipated to facilitate structured study outputs.[104–106] We will apply the framework method within the sounds of silence framework to enable us to clearly and concisely communicate the experiences of men who have lived through multiple miscarriages, and to inform the design and delivery of interventions intended to support them.

Transcriptions will be imported into NVivo[107] software to facilitate data management. First they will be familiarised by the study team, and then re-examined line by line to apply inductive paraphrases as descriptive or conceptual codes. Collectively these codes will represent a comprehensive index to underpin interpreted meanings and to identify patterns such as themes and subthemes in the data collected.[104 105] The research team will also use field notes to generate analytic memos as appropriate to inform the analysis.[104] Study data will then be charted into a matrix to map the interpretations by case participant and by conceptual idea, and to distil important results and recommendations.[104 105 108]

Thus we hope for rich and robust interpretations of perceptions perhaps previously unidentified or silenced, to newly elucidate thoughts and behaviours at play in contemporary experiences of multiple miscarriages.[104 106] The knowledge generated by our study may also help to answer more deductive questions to arise from those with interests within the scope of these issues. Our theoretical orientation upholds a commitment to development beyond original disclosure, and we will continue to collaborate with NHS and charitable partners, to inform the practice of these and other stakeholders in miscarriage support.

Patient and public involvement

Our research to date has been enriched by continuous consultation with an advisory panel of men and women with experiences of multiple miscarriages, other NHS service users, bereavement midwives and patient experience managers at our clinical study site, alongside representatives of charitable organisations and peer support forums active in miscarriage research and support. These stakeholders will remain actively engaged in study oversight throughout the lifetime of the project, via regular advisory meetings to enable us to voice and work with silences now and in the future.

Ethics and dissemination

Regulatory compliance

Our study protocol version 2.0 dated 19 July 2019 received a favourable opinion from the West Midlands South Birmingham Research Ethics Committee on behalf of the Health Research Authority of the UK (reference 16/WM/0423). Any amendments will be authorised in advance of implementation, and recorded in communication with the research governance team of the project sponsor and regulatory bodies as appropriate. The study is registered and researchers will adhere to recommendations to report transparently and completely for the benefit of all relevant stakeholders.[109 110]

Risk assessment and management

Study investigators and clinicians will maintain up-to-date training in good clinical practice,[111] and make every effort to remain respectful of the autonomy, privacy and dignity of all contributors to the research. The project will collect personal data and explore subject matter that could possibly engender emotional distress. However, the associated risk will be mitigated and participants safeguarded wherever possible. The wellbeing of participants and researchers will always be prioritised ahead of the value of the study to generate new knowledge.

Emotional welfare

Prospective contributors will be encouraged to consider the decision carefully, informed by written literature and verbal discussion to explain that contribution is entirely voluntary. The investigative team will be continuously vigilant to ongoing consent, and psychosocial support will be signposted as necessary. Indications of emotional distress will be managed via a pathway adopted and effective in previous studies.[112] Any participant who appears to be upset will be invited to take time out. The research team will manage any immediate risk and recommend individuals to liaise with relevant services such as the bereavement support team of our clinical study site, and miscarriage charities, if appropriate.

Data security

To prevent inadvertent loss or disclosure of personally identifiable or other information, all study data will be managed to comply robustly with the European Union General Data Protection Regulation 2016/679[113] and Data Protection Act 2018.[114] Consent forms, demographic questionnaires, audio-recordings, transcriptions and field notes will be held securely in the custody of the chief investigator for 10 years after first publication of the project findings.

Dissemination

Information about our rationale, aims and methods will be available from a dedicated webpage to be hosted by the study sponsor throughout the lifetime of the project.[115] The research team will also make the study findings available without any unnecessary delay through a range of scientific and lay media.

Scientific media

The findings of our research will be reported in the form of a doctoral research thesis, and submitted for publication as academic manuscripts, and for presentation at national and international conferences. If the academic manuscripts cannot be issued openly via commercial publishers, they will be made openly available via a dedicated online repository hosted by the study sponsor.

Lay media

In order to ensure the study findings gain maximum impact beyond the academic community, we will liaise with our NHS and charitable collaborators to communicate the results via meetings, newsletters, webpages, posters, and other relevant events and resources of these organisations.

Subsequent to first publication, we will consider external requests to obtain anonymised study data, subject to a mutually satisfactory data sharing agreement to establish the rights and responsibilities of each party.

Supplementary Material

Reviewer comments

bmjopen-2019-035967.reviewer_comments.pdf (556.1KB, pdf)

Author's manuscript

bmjopen-2019-035967.draft_revisions.pdf (826.6KB, pdf)

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Association and other charitable organisations active in miscarriage research and support.

Footnotes

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Contributors: AC is the director of Tommy's National Centre for Miscarriage Research, and chief investigator of the study. LLJ and AET guided methodological decisions necessary to design the project, and will oversee implementation. With the support of coauthors, HMW drafted the detailed study protocol, participant information literature and this manuscript. All authors contributed to critical revisions of the detailed study protocol, participant information literature and this manuscript. All authors also reviewed the final manuscript.

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Competing interests: None declared.

Patient and public involvement: Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Please refer to the Methods section for further details.

Patient consent for publication: Not required.

Ethics approval: West Midlands South Birmingham Research Ethics Committee: 16/WM/0423.

Provenance and peer review: Not commissioned; externally peer reviewed.

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Associated Data

This section collects any data citations, data availability statements, or supplementary materials included in this article.

Supplementary Materials

Reviewer comments

bmjopen-2019-035967.reviewer_comments.pdf (556.1KB, pdf)

Author's manuscript

bmjopen-2019-035967.draft_revisions.pdf (826.6KB, pdf)
