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

Submission date 30/08/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol
Registration date 03/09/2019	**Overall study status** Completed	☐ Statistical analysis plan ☐ Results
Last Edited 11/10/2024	**Condition category** Pregnancy and Childbirth	☐ Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background

Miscarriage is common, but the emotional effects often go unrecognised and unsupported. Men are also presupposed to be emotionally less affected than women because they do not experience the biological effects of miscarriage, and because many people consider masculinity to mean absence of emotion. However many men describe feelings of disorientation and fear during and after miscarriage. Men who experience multiple miscarriages may also find grief and anxiety intensified by loss of hope for any healthy pregnancy in the future.

Study aims

Studies of the experiences of men who have lived through multiple miscarriages are limited. Therefore we aim to explore and better understand the experiences and any support requirements of men with a history of repeated pregnancy loss.

Who can participate?

We will interview men with a history of two or more miscarriages, to listen and learn about these experiences. The participants will be invited by healthcare practitioners at a large urban hospital with a recurrent miscarriage clinic, and by advertisements to be disseminated by miscarriage charities, in the United Kingdom.

What does the study involve?

Between 30 and 50 semi-structured telephone interviews with consented individuals will be audio-recorded, transcribed into written form and anonymised prior to analysis. Then the interpretations of the research team will be presented to the study participants, to enable them to clarify or correct these findings.

What are the possible benefits and risks of participating?

Contribution to this study will enable men living through multiple miscarriages to talk about their experiences, and to communicate their thoughts and feelings to an interested, non-judgemental listener. We also hope for the study findings to influence policy and practice in the management of multiple miscarriages.

Many people value the opportunity to be heard, but our subject matter is potentially emotive. If participants experience any distress then it will be possible for them to take a break or discontinue participation completely. Psychosocial support will be signposted in participant information literature and in other communications as necessary. The investigative team will be continuously vigilant to ongoing consent, and indications of emotional distress will be managed via a pathway developed in previous studies to ensure appropriate empathy.

Although contribution to the study will take up some time for interview and focus group discussion, every effort will be made to suit the convenience of participants. We will be happy to interview in the morning, afternoon or evening, and any day of the week. Men will also receive a £20 honorarium (digital high street voucher) as a token of appreciation for the time and effort contributed.

Where is the study run from?
Birmingham Women’s and Children’s Hospital, UK

When is the study starting and how long is it expected to run for?
October 2019 to September 2023

Who is funding the study?
Tommy's, UK

Who is the main contact?
Helen Williams
hmw471@student.bham.ac.uk

Study website
https://www.birmingham.ac.uk/research/activity/mds/centres/maternal-health/research/experiences.aspx

Contact information

Type(s)
Public

Contact name
Miss Helen Williams

ORCID ID
http://orcid.org/0000-0003-4417-9404

Contact details
University of Birmingham
Birmingham
United Kingdom
B15 2TT
+44(0)121 414 8504
hmw471@student.bham.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
University of Birmingham ERN 16-0123, REC 16/WM/0423

Study information

Scientific Title
Men Living Through Multiple Miscarriages: A Qualitative Exploration of Experiences and Support Requirements

Study objectives
What are the experiences and any support requirements of men living through multiple miscarriages?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/08/2019, West Midlands South Birmingham Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +44207 104 8108; NRESCommittee.westmidlands-southbirmingham@nhs.net), ref: 16/WM/0423

Study design
Qualitative study

Primary study design
Other

Secondary study design

Study setting(s)
Home

Study type(s)
Other

Participant information sheet
https://www.birmingham.ac.uk/Documents/college-mds/research/Men-Living-Through-Multiple-Miscarriages-Participant-Information-Leaflet-Version-2.0.pdf

Health condition(s) or problem(s) studied
Multiple (two or more) miscarriages before 16 weeks of gestation

Interventions
Our qualitative study design is underpinned by the sounds of silence framework previously developed by Serrant-Green: primary data will be collected via semi-structured telephone interviews and interpreted via the framework method (Ritchie and Lewis) with a focus group discussion to enable member synthesis.

Men will be invited to participate in the study by healthcare practitioners at a large urban hospital with a recurrent miscarriage clinic, and by advertisements to be disseminated by miscarriage charities, in the United Kingdom.

Work Package 1
Informed by the sounds of silence framework, semi-structured telephone interviews will enable participants to communicate their experiences of multiple miscarriages freely enough to yield rich textual data, but without undue diversion to issues beyond the scope of our study objectives. Natural dialogue will be supported by a discussion guide with appropriate prompts where required. The interviews are anticipated to last up to 60 minutes each. They will be digitally audio-recorded and transcribed verbatim. The study team will review each transcription to ensure accuracy and to anonymise any personally identifiable data prior to analysis.

Work Package 2
Different voices and silences are audible to different people, so we will adopt the principles of member synthesis to enable the sample population to clarify and elaborate or reconstruct our preliminary interpretations of interview data. A face-to-face focus group discussion of up to 120 minutes will be arranged and facilitated to encourage constructive contributions from everybody. The dialogue will be digitally audio-recorded and transcribed verbatim. The study team will review the transcription to ensure accuracy and to anonymise any personally identifiable data prior to further analysis.

Intervention Type
Other

Primary outcome measure
We will generate evidence of the experiences and any support requirements of men living through multiple miscarriages. Qualitative study data will be collected as audio-recordings of semi-structured telephone interviews (each 60 minutes) and then a focus group discussion (120 minutes), alongside reflexive journal entries of the researchers throughout the lifetime of the study. They will be supplemented by demographic information to be collected in a proforma questionnaire to facilitate maximum variation among the recruited sample and to contextualise any findings.

Data collection and analysis within the scope of Work Package 1 will continue concurrently until saturation is sufficient to provisionally satisfy our study objectives. However, we anticipate all data collection to be complete with approximately 24 months.

Secondary outcome measures
N/A

Overall study start date
01/07/2019

Completion date

30/09/2023

Eligibility

Key inclusion criteria

1. Male
2. Aged 18 years or more
3. Experience of two or more clinically confirmed pregnancies that both ended spontaneously before 16 completed weeks of gestation
4. Able to hold a conversation in English
5. Able and willing to give informed consent to participate in an audio-recorded telephone interview

Participant type(s)

Mixed

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

30 - 50

Total final enrolment

30

Key exclusion criteria

1. More than 12 months since most recent miscarriage (to ensure relevance to current clinical practice)
2. Infertility diagnosis (to eliminate confusion with experiences of infertility)

Date of first enrolment

01/10/2019

Date of final enrolment

30/05/2021

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Birmingham Women’s and Children’s Hospital
Mindelsohn Way
Birmingham
United Kingdom
B15 2TG

Sponsor information

Organisation
University of Birmingham

Sponsor details
Research Governance and Integrity
Research Support Group
Room 119 Aston Webb Building
University of Birmingham
Birmingham
England
United Kingdom
B15 2TT
+44 (0) 121 415 8011
researchgovernance@contacts.bham.ac.uk

Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Tommy's

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Study findings will be owned by the University of Birmingham and disseminated with a focus on the experiences and any support requirements of men living through multiple miscarriages. They may also be used to inform the development of future funding proposals, and to facilitate the continuous professional development of healthcare practitioners at Birmingham Women's and Children's Hospital or beyond, via presentation and discussion at clinical team meetings or conferences.

1. Information about the rationale, aims and methods of the study will be available from webpages of the University of Birmingham throughout the lifetime of the project
2. Study findings will be reported in the form of a doctoral research thesis and academic manuscripts, to be supplemented by presentations at relevant conferences. The manuscripts will be also made openly available via a dedicated online repository hosted by the University of Birmingham for this purpose
3. In order to ensure the study findings gain maximum impact beyond the academic community, researchers will liaise with dedicated professional services such as press and communications teams at the University of Birmingham, to bring male experiences of multiple miscarriages to the attention of a wider audience
4. Media engagement will be further supported by the Communications Director of Birmingham Women's and Children's Hospital, and by the Marketing and Communications Manager of Tommy's
5. Public impact will be promoted by proactive engagement of the research team with local lay forums such as the Family and Patient Advisory Council of Birmingham Women's and Children's Hospital, and with national miscarriage charities such as Tommy's and the Miscarriage Association

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available from the corresponding author on reasonable request.

The final study dataset will comprise consent forms, demographic questionnaires, audio-recordings and transcripts of data collection events, and field notes. These data will be accessible only to the research team, the Sponsor and relevant regulatory authorities. However, the research team will make the findings of the study freely available through publication or other dissemination tools without any unnecessary delay. The findings will be accompanied by an honest, accurate and transparent account of the study methods.

Permission for anonymised data to be shared for the purpose of future academic research will be sought from all participants prior to any data collection. Then for ten years after first publication of the findings, the research team will consider external requests to obtain anonymised study data only, to be securely shared under the auspices of the Chief Investigator [Professor Arri Coomarasamy: a.coomarasamy@bham.ac.uk]. All requesters wishing to obtain any part of the dataset will be asked to provide a brief research proposal to summarise objectives and timelines of the candidate project, intellectual property rights, and expectations for publications and citations. These details will form the basis of a Data Sharing Agreement between the University of Birmingham and the requester, to clearly establish the responsibilities of each party. It is expected that requesters will, as a minimum, acknowledge the original research team and Tommy's funding for the study, and will consider co-authorship of any subsequent publications, if appropriate.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	15/05/2020	18/05/2020	Yes	No
HRA research summary			28/06/2023	No	No