

# BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email [info.bmjopen@bmj.com](mailto:info.bmjopen@bmj.com)

# BMJ Open

## Men Living Through Multiple Miscarriages: Protocol for a Qualitative Exploration of Experiences and Support Requirements

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-035967
Article Type:	Protocol
Date Submitted by the Author:	24-Nov-2019
Complete List of Authors:	Williams, Helen; University of Birmingham, Tommy's National Centre for Miscarriage Research; University of Birmingham, Institute of Clinical Sciences Jones, Laura; University of Birmingham, Institute of Applied Health Research Coomarasamy, Arri; University of Birmingham, Tommy's National Centre for Miscarriage Research; University of Birmingham, Institute of Metabolism and Systems Research Topping, AE; University of Birmingham, Institute of Clinical Sciences; University Hospitals Birmingham NHS Foundation Trust
Keywords:	GYNAECOLOGY, PUBLIC HEALTH, QUALITATIVE RESEARCH

SCHOLARONE™  
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1 Men Living Through Multiple Miscarriages:  
2  
3 Protocol for a Qualitative Exploration of Experiences and Support Requirements  
4

---

5  
6  
7 **ABBREVIATED TITLE**  
8

9 Men Living Through Multiple Miscarriages  
10  
11  
12

13 **AUTHORS AND AFFILIATIONS**  
14

15 **Helen M Williams,<sup>1,2\*</sup> Laura L Jones,<sup>3</sup> Arri Coomarasamy<sup>4</sup> and Annie Topping,<sup>3,5</sup>**  
16

17  
18 <sup>1</sup>Tommy's National Centre for Miscarriage Research, University of Birmingham, Edgbaston, Birmingham B15 2TT, United  
19 Kingdom  
20

21 <sup>2</sup> Institute of Clinical Sciences, University of Birmingham, Edgbaston, Birmingham B15 2TT, United Kingdom  
22

23 <sup>3</sup> Institute of Applied Health Research, University of Birmingham, Edgbaston, Birmingham B15 2TT, United Kingdom  
24

25 <sup>4</sup> Institute of Metabolism and Systems Research, University of Birmingham, Edgbaston, Birmingham B15 2TT, United Kingdom  
26

27 <sup>5</sup> University Hospitals Birmingham NHS Foundation Trust, Edgbaston, Birmingham B15 2TH, United Kingdom  
28

29 \* Corresponding author, h.m.williams.1@bham.ac.uk, 07947 619 960  
30  
31

32  
33 **WORD COUNT, EXCLUDING TITLE PAGE, ABSTRACT, REFERENCES, FIGURES AND TABLES**  
34

35 [2,969 not including acknowledgements etc]  
36

37 [3,163 including acknowledgements etc]  
38  
39

40  
41 **KEYWORDS**  
42

43 Fathering, fathers, focus groups, framework method, masculinity, miscarriage, pregnancy, recurrent miscarriage, social  
44 marginalisation, silences framework, telephone interviews.  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

# Men Living Through Multiple Miscarriages:

## Protocol of a Qualitative Exploration of Experiences and Support Requirements

---

### 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.

#### Methods and Analysis

Our qualitative study will adopt the silences 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 NHS hospital in England, and from advertisements to be disseminated by miscarriage charities in the United Kingdom.

Telephone interviews supported by a semi-structured discussion guide will be audio-recorded, transcribed and anonymised. The transcriptions and any fieldnotes will be interpreted by the framework method of Ritchie and Lewis embedded within the silences framework. Tentative findings will be presented to research participants at a 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 NHS collaborators and miscarriage charities. Outputs are anticipated to inform future policy and practice in the management of multiple miscarriages.

#### Registration

ISRCTN 21828561.

#### STRENGTHS AND LIMITATIONS

- Our adoption of a qualitative approach is anticipated to enrich our insight to experiences unexplored to date.
- The silences framework of our qualitative study design will enable voices previously silent or unheard to be acknowledged.

- 1     ▪ Individual telephone interviews are expected to provide participants with a safe space to disclose previously
- 2       marginalised experiences.
- 3
- 4     ▪ Member synthesis will optimise the authenticity of our findings: to inform policy and practice in the supply of
- 5       support for men living through multiple miscarriages.
- 6
- 7     ▪ Participants will be recruited from a single NHS site and advertisements to be disseminated by special interest
- 8       charities.
- 9

## 12 INTRODUCTION

14 Miscarriage, the loss of pregnancy before survival outside the womb becomes possible at around 24 weeks of gestation, is  
15 prevalent.<sup>1</sup> Many cases go unreported but there is evidence to suggest that more than 200,000 pregnancies end in  
16 miscarriage every year in the United Kingdom.<sup>2</sup> Moreover as many as 1 in 20 couples experience more than a single loss.<sup>3</sup>

19 Most miscarriages occur during the first trimester<sup>4</sup> before there is any visible sign of pregnancy and possibly before  
20 pregnancy is perceptible by gynaecological ultrasound.<sup>5</sup> Consequently many of these early miscarriages remain unknown and  
21 unrecognised. In other cases they remain unspoken or silenced to prevent embarrassment and stigma<sup>6-9</sup> engendered by an  
22 outcome that is unplanned and frequently unexplained,<sup>10,11</sup> or because intimate body functions and messy biological  
23 symptoms<sup>12</sup> are taboo.<sup>13</sup> As a result the psychosocial effects often remain unacknowledged and unsupported.<sup>6-9,14-22</sup>

27 Marginalisation may be more acutely experienced by men because the biological sequelae of miscarriages are confined to  
28 women, and because men often find themselves cast into gender roles characterised by emotional detachment and  
29 rationality.<sup>23</sup> Yet miscarriages may bring disorientation, anxiety and other difficult feelings to either or both partners.<sup>21,23-26</sup>  
30 Some of these emotions and uncertainties may be intensified by recurrence:<sup>27</sup> those who encounter repeated miscarriages  
31 may be affected by fear of chronic pathology and loss of hope for any healthy pregnancy in the future.<sup>27-31</sup>

35 The National Bereavement Care Pathway<sup>32</sup> underpins ongoing improvements in professional capability and practice to offer  
36 psychosocial support, but resources are limited and perhaps not accessible to everybody.<sup>22,33-36</sup> Interventions and services  
37 may be prioritised toward later miscarriages or stillbirth accommodated in obstetric facilities not early pregnancy units<sup>25,33</sup> or  
38 toward only women as the rightful recipients of care.<sup>23,37</sup> Some clinicians also describe inadequate time or instruction to bear  
39 the burden of emotional labour.<sup>15,20,22,38</sup> Consequently it is unsurprising that many individuals and families report inadequate  
40 information and emotional support to navigate early miscarriages.<sup>14,16,20,22</sup> They also advocate more research to better  
41 understand the psychosocial consequences.<sup>39</sup>

46 Most of the previous studies adopt quantitative measurements of distress among women.<sup>27-31,40</sup> There are fewer qualitative  
47 studies,<sup>41</sup> and even fewer to focus on experiences among men.<sup>23</sup> We recently published a systematic review and thematic  
48 synthesis of 22 qualitative studies with any male participants who had lived through one or more miscarriages. We were  
49 unable to identify any previous research dedicated to examine the effects of more than a single loss among men.<sup>23</sup> The  
50 European Society of Human Reproduction and Embryology has observed the gap in the evidence and recommended  
51 investigative action to remedy it.<sup>42</sup> This manuscript presents the protocol of an empirical study designed to explore male  
52 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.

## METHODS AND ANALYSIS

### Theoretical Orientation and Study Design

We will adopt a qualitative approach to understand meanings and to explore ideas more freely and deeply than we could hope via quantitative measurement.<sup>43-46</sup> Our theoretical orientation is underpinned by a recognition that lived experiences are socially constructed<sup>13,47-49</sup> and mediated by uneven power relations between different people.<sup>50,51</sup> The recognition is built upon previous studies of male experiences of one or more miscarriages<sup>23</sup> and other studies of sensitive subjects and populations possibly marginalised. Serrant-Green<sup>52</sup> identified sounds of silence<sup>52,53</sup> in beliefs and behaviours that are invisible, little understood or acknowledged 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 intended to facilitate awareness of issues important to our study participants and possibly previously silenced.

<FIGURE 1>

### Figure 1: Data Collection and Analysis Embedded within the Silences Framework<sup>52,53</sup>

In order to overcome the difficulties associated with recruitment among possibly marginalised<sup>54</sup> 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.<sup>55</sup> We seek to recruit men who have lived through two or more pregnancies that were clinically confirmed by ultrasonic data 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 toward obstetric facilities.<sup>36</sup> 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.

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

**Table 1: Inclusion and Exclusion Criteria**

Our previous research<sup>23</sup> and consultations with members of the target population suggest that psychosocial responses to miscarriages may be influenced by perceptions of parenthood.<sup>23</sup> Hence we will recruit purposively<sup>56</sup> 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.<sup>57,58</sup>

## Recruitment

Men will be invited to participate in the study by healthcare practitioners located at the recurrent miscarriage clinic of a large tertiary 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 dedicated webpages of the University of Birmingham. The webpages with information about the study will be advertised via newsletters, tweets and other social media of the University of Birmingham and charitable organisations active in miscarriage research and support. The webpages may also be signposted by those already recruited. We recognise possibilities for chain referral to result in a narrow demographic range so we will aim for broad dissemination through charitable partners to forestall dependency on a snowball effect.<sup>54</sup>

## Informed Consent

Subsequent to introductions and expressions of interest, the research team will liaise with prospective participants by email, telephone and/or 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 data are anonymised and assimilated to the 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.<sup>60-63</sup> Table 2 describes our preparations to facilitate recruitment without undue loss of fidelity to ethical principles of voluntary participation, research integrity and transparency.<sup>63,64</sup>

<b>Issue of Information</b>	<b>Completion of Consent Form</b>	<b>Return of Consent Form</b>
<b><i>In advance of interview</i></b>		
Postal delivery	Fill and sign in wet ink by hand	Scan and email as attachment/s <b>OR</b>
Email with attachment/s	Print, fill and sign in wet ink by hand <b>OR</b> Complete, sign and save electronically	Photograph and email as attachment/s <b>OR</b> Pre-paid postal delivery
Secure online survey interface <sup>59</sup>	Complete and sign online	Submit online
<b><i>At the beginning of audio-recorded interview if methods above are unfeasible</i></b>		
Read out line-by-line	Respond verbally to each item	Not applicable

**Table 2: Methods of Informed Consent**

## **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 semi-structured interview via telephone within our work package 1. Semi-structured interactions will enable informants to tell us their stories<sup>65</sup> freely enough to yield rich textual data, but without undue diversion to issues beyond the scope of our study objectives.<sup>57</sup> Semi-structured dialogue will also enable investigators to compare different stories more easily than unstructured discussions.<sup>57,66</sup> Interpersonal rapport is essential to an effective qualitative interview, and recent studies refute the historical criticism that it is difficult to establish empathy<sup>67,68</sup> via telephone. There is further evidence to suggest that telephone communication may facilitate a sense of anonymity, privacy and freedom, conferring more relational power to interviewees.<sup>69-73</sup> Telephone interviews offer logistic convenience and feasibility to extend the geographical range of the study population,<sup>69-72,74,75</sup> and they reduce any personal safety risks to the interviewer.<sup>69,71</sup>

Our interviews are anticipated to last up to 60 minutes each. Ongoing consent will be verified and then a semi-structured discussion guide will support a purposeful conversation with appropriate prompts when required.<sup>76</sup> 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.

1 <FIGURE 2>

2  
3  
4 **Figure 2: Indicative Contents of Semi-structured Interviews**

5  
6 All audio-recordings will be transcribed verbatim by specialist transcription suppliers subject to confidentiality agreements to  
7 prevent disclosure to third parties. The study team will review each transcription to ensure accuracy and to anonymise any  
8 personally identifiable data. Then the textual contents will be interpreted and preliminary findings will be presented to study  
9 participants for member synthesis within our work package 2.  
10  
11

12  
13  
14 **Data Collection in Work Package 2: Focus Group Discussion**

15  
16 Different voices and silences are audible to different people<sup>52,53</sup> so within our work package 2 we will undertake member  
17 synthesis<sup>52,53,77,78</sup> to enable study participants to elaborate or reconstruct our preliminary interpretations of interview data.<sup>77-79</sup>  
18 A face-to-face focus group discussion will be facilitated at an accessible location in central England to explore whether or not  
19 stories heard and reported by researchers resonate with perceptions among the sample population. We anticipate a  
20 collective dialogue to elucidate similarities and differences between individual experiences, with additional opportunities to  
21 learn from discursive interactions among the members.<sup>80-85</sup>  
22  
23

24  
25 Invitations will be issued to all study participants by email, telephone, SMS and/or post. Contributions will remain entirely  
26 voluntary and ongoing consent will be verified verbally on the day. After consent is confirmed our preliminary findings in the  
27 form of tentative themes and descriptive or explanatory conclusions will be presented for confirmation or refutation with  
28 new insights and interpretations. Members will be invited to reflect and comment, and to consider any implications for  
29 further research or other action.  
30  
31

32  
33 Our focus group discussion is expected to last for up to 120 minutes, supported by a semi-structured guide if required to  
34 encourage constructive contributions from everybody.<sup>80,81,86,87</sup> The event will be audio-recorded, transcribed verbatim and  
35 anonymised for further analysis.  
36  
37  
38  
39

40 **Data Collection in Work Packages 1 and 2: Honoraria and Expenses**

41  
42 All men recruited to the study will be entitled to receive a small honorarium in recognition of the time and effort incurred in  
43 interview participation, and a further honorarium for contribution to focus group discussion. Each of these honoraria will take  
44 the form of a £20 digital high street voucher to be issued after data collection. Participants in the focus group discussion will  
45 also be entitled to reclaim reasonable travel expenses.  
46  
47  
48  
49

50 **Data Analysis**

51  
52 Our study data collected in interviews and focus group discussion will be examined and interpreted via the framework  
53 method established by Ritchie and Lewis<sup>88</sup> and further described by Gale.<sup>89</sup> The framework method is sufficiently flexible to  
54 suit different theoretical positions and adaptable to inductive or deductive analyses.<sup>89,90</sup> It is also anticipated to facilitate  
55 structured study outputs.<sup>88-90</sup> We will apply the framework method within the silences framework to enable us to clearly and  
56 concisely communicate the experiences of men who have lived through multiple miscarriages, and to inform the design and  
57 delivery of interventions intended to support them.  
58  
59  
60

1 Transcriptions will be imported into nVivo<sup>91</sup> software to facilitate data management. First they will be familiarised by the study  
2 team, and then re-examined line-by-line to apply inductive paraphrases as descriptive or conceptual codes. Collectively these  
3 codes will represent a comprehensive index to underpin interpreted meanings and to identify patterns such as themes and  
4 subthemes in the data collected.<sup>88,89</sup> The research team will also use field notes to generate analytic memos as appropriate to  
5 inform the analysis.<sup>88</sup> Study data will then be charted into a matrix to map the interpretations by case participant and by  
6 conceptual idea, and to distil important results and recommendations.<sup>88,89,92</sup>

7  
8 Thus we hope for rich and robust interpretations of perceptions perhaps previously unidentified, to newly elucidate thoughts  
9 and behaviours at play in contemporary experiences of multiple miscarriages.<sup>88,90</sup> The knowledge generated by our study may  
10 also help to answer more deductive questions to arise from those with prior and specific interests within the scope of these  
11 issues. Our theoretical orientation additionally upholds a commitment to development beyond original disclosure: we will  
12 continue to collaborate with NHS and charitable partners, to inform the practice of these and other stakeholders in  
13 miscarriage support.

## 14 PATIENT AND PUBLIC INVOLVEMENT

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

## 20 ETHICS AND DISSEMINATION

### 21 Regulatory Compliance

22 Our study protocol version 2.0 dated 19<sup>th</sup> July 2019 has received a favourable opinion from the West Midlands South  
23 Birmingham Research Ethics Committee on behalf of the Health Research Authority of the United Kingdom (reference  
24 16/WM/0423). Any amendments will be authorised in advance of implementation, and recorded in communication with the  
25 research governance team of the University of Birmingham in the role of sponsor, and with regulatory bodies as appropriate.  
26 The project is registered (ISRCTN 21828561) and researchers will adhere to recommendations to report transparently and  
27 completely for the benefit of all relevant stakeholders.<sup>93,94</sup>

### 28 Risk Assessment and Management

29 Our study investigators and clinicians will maintain up-to-date training in good clinical practice<sup>95</sup> and make every effort to  
30 remain respectful of the autonomy, privacy and dignity of all contributors to the research. The project will collect personal  
31 data and explore subject matter that could possibly engender emotional distress. However the associated risks will be  
32 mitigated and participants safeguarded wherever possible. The wellbeing of participants and researchers will always be  
33 prioritised ahead of the value of the study to generate new knowledge.

1       ▪   **Emotional Welfare**

2       Prospective research participants will be encouraged to consider the decision carefully, informed by written  
3       literature and verbal discussion to explain that contribution is entirely voluntary. The investigative team will be  
4       continuously vigilant to ongoing consent, and psychosocial support will be signposted as necessary. Indications of  
5       emotional distress will be managed via a pathway adopted and effective in previous studies.<sup>96</sup>

6       ▪   **Data Security**

7       To prevent inadvertent loss or disclosure of personally identifiable or other information, all study data will be  
8       managed to comply robustly with the EU General Data Protection Regulation 2016/679<sup>97</sup> and Data Protection Act  
9       2018.<sup>98</sup> Consent forms, demographic questionnaires, audio-recordings, transcriptions and field notes will be held  
10       securely in the custody of the Chief Investigator for 10 years after first publication of the project findings.

## 17   Dissemination and Data Sharing

18   Information about the rationale, aims and methods of the study will be available from webpages of the University of  
19   Birmingham throughout the lifetime of the project.<sup>99</sup> The research team will also make the findings of the study available  
20   without any unnecessary delay through a range of scientific and lay media.

21       ▪   **Scientific Media**

22       Study findings will be reported in the form of a doctoral research thesis, and submitted for publication as academic  
23       manuscripts, and for presentation at national and international conferences. If the academic manuscripts cannot be  
24       issued openly via commercial publishers, they will be made openly available via a dedicated online repository hosted  
25       by the University of Birmingham.

26       ▪   **Lay Media**

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

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

## 38   CONCLUSION

39   Many women and partners experience multiple miscarriages, and these events often bring psychosocial consequences. In the  
40   absence of any biomedical reason for candidacy to receive clinical care or other support,<sup>35</sup> the effects on men may be  
41   marginalised or silenced. This study adopts qualitative methods to hear and understand any silences created and perpetuated  
42   by social expectations of men in the context of miscarriages. We do not expect any single universal story to be told because  
43   individual experiences may be influenced by vastly different social circumstances. We also recognise that diversity presents a  
44   challenge to those offering help, especially amid ongoing growth in public expectations of person-centred care.<sup>100</sup> However  
45   we aim to identify and better understand any commonalities in the experiences and support requirements of men with a  
46   history of repeated early pregnancy loss. Our preliminary interpretations will be clarified and enriched by member synthesis to  
47   bring greater fidelity to the meanings intended and communicated by the participants. Our new knowledge and outputs will  
48   assist efforts to design and deliver interventions to help them.

## ACKNOWLEDGMENTS

The authors extend many thanks to members of the patient and public advisory panel dedicated to the study. These members include men and women with experiences of multiple miscarriages, other NHS service users and practitioners, and representatives of Tommy's, the Miscarriage Association and other charitable organisations active in miscarriage research and support.

## AUTHOR CONTRIBUTIONS

AC is the Director of Tommy's National Centre for Miscarriage Research, and Chief Investigator of the study. LLJ and AT guided methodological decisions necessary to design the project, and will oversee implementation. With the support of co-authors, 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.

## FUNDING STATEMENT

This study is partially financially supported by Tommy's National Centre for Miscarriage Research. The funders will take no role in study design, data collection and analysis, decision to publish, or preparation of publications.

## COMPETING INTERESTS STATEMENT

The authors declare no conflicts of interest.

## PARTICIPANT CONSENT

Informed consent will be obtained from all study participants.

## ETHICAL REVIEW

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

## REFERENCES

1. RCOG. The Investigation and Treatment of Couples with Recurrent First-trimester and Second-trimester Miscarriage. In: National Institute for Health and Care Excellence, editor. London: RCOG; 2011.
2. Bottomley C. Epidemiology and aetiology of miscarriage and ectopic pregnancy. In: Jurkovic D, Farquharson RG, editors. Acute Gynaecology and Early Pregnancy. London: RCOG Press; 2011. p. 11-22.
3. Rai R, Regan L. Recurrent miscarriage. *The Lancet*. 2006;368(9535):601-11.
4. Brigham SA, Conlon C, Farquharson RG. A longitudinal study of pregnancy outcome following idiopathic recurrent miscarriage. *Human Reproduction*. 1999;14(11):2868-71.
5. Jauniaux E, Johns J, Burton GJ. The role of ultrasound imaging in diagnosing and investigating early pregnancy failure. *Ultrasound Obstet Gynecol*. 2005;25(6):613-24.

- 1 6. Hazen MA. Societal and workplace responses to perinatal loss: Disenfranchised grief or healing connection. *Human*  
2 *Relations*. 2003;56(2):147-66.
- 3 7. Renner CH, Verdekal S, Brier S, Fallucca G. The meaning of miscarriage to others: Is it an unrecognized loss? *Journal of*  
4 *Personal & Interpersonal Loss*. 2000;5(1):65-76.
- 5 8. Rowlands IJ, Lee C. The silence was deafening: Social and health service support after miscarriage. *Journal of*  
6 *Reproductive and Infant Psychology*. 2010;28(3):274-86.
- 7 9. Wojnar DM, Swanson KM, Adolfsson A-S. Confronting the inevitable: A conceptual model of miscarriage for use in  
8 clinical practice and research. *Death Studies*. 2011;35(6):536-58.
- 9 10. Garrido-Gimenez C, Alijotas-Reig J. Recurrent miscarriage: causes, evaluation and management. *Postgraduate Medical*  
11 *Journal*. 2015;91:151-62.
- 12 11. Saravelos SH, Li TC. Unexplained recurrent miscarriage: how can we explain it? *Hum Reprod*. 2012;27(7):1882-6.
- 13 12. Miscarriage Association. Management of miscarriage: your options. Wakefield: Miscarriage Association; 2016.
- 14 13. Lou S, Frumer M, Schlutter MM, Petersen OB, Vogel I, Nielsen CP. Experiences and expectations in the first trimester of  
15 pregnancy: a qualitative study. *Health Expect*. 2017;20(6):1320-9.
- 16 14. Brier N. Understanding and managing the emotional reactions to a miscarriage. *Obstetrics and Gynecology*.  
17 1999;93(1):151-5.
- 18 15. Evans R. Emotional care for women who experience miscarriage. *Nursing Standard*. 2012;26(42):35-41.
- 19 16. Frost M, Condon JT. The psychological sequelae of miscarriage: a critical review of the literature. *Aust N Z J Psychiatry*.  
20 1996;30(1):54-62.
- 21 17. Geller PA, Psaros C, Kornfield SL. Satisfaction with pregnancy loss aftercare: Are women getting what they want?  
22 *Archives of Women's Mental Health*. 2010;13(2):111-24.
- 23 18. Layne LL. Motherhood lost: Cultural dimensions of miscarriage and stillbirth in America. *Women and Health*. 1990;16(3-  
24 4):69-98.
- 25 19. Lee C, Slade P. Miscarriage as a traumatic event: A review of the literature and new Implications for intervention. *Journal*  
26 *of Psychosomatic Research*. 1996;40(3):235-44.
- 27 20. Randolph AL, Hruba BT, Sharif S. Counseling Women Who Have Experienced Pregnancy Loss: A Review of the  
28 Literature. *Adultspan Journal*. 2015;14(1):2-10.
- 29 21. van den Akker OBA. The psychological and social consequences of miscarriage. *Expert Review of Obstetrics and*  
30 *Gynecology*. 2011;6(3):295-304.
- 31 22. van den Berg MMJ, Dancet EAF, Erlikh T, van der Veen F, Goddijn M, Hajenius PJ. Patient-centered early pregnancy care:  
32 a systematic review of quantitative and qualitative studies on the perspectives of women and their partners. *Human*  
33 *Reproduction Update*. 2018;24(1):106-18.
- 34 23. Williams HM, Topping A, Coomarasamy A, Jones LL. Men and Miscarriage: A Systematic Review and Thematic Synthesis.  
35 *Qualitative Health Research*. 2019;1049732319870270.
- 36 24. Brier N. Anxiety After Miscarriage: A Review of the Empirical Literature and Implications for Clinical Practice. *Birth*.  
37 2004;31(2):138-42.
- 38 25. Brier N. Grief following miscarriage: a comprehensive review of the literature. *Journal of Women's Health*.  
39 2008;17(3):451-64.
- 40 26. Radford EJ, Hughes M. Women's experiences of early miscarriage: implications for nursing care. *Journal of Clinical*  
41 *Nursing*. 2015;24(11-12):1457-65.
- 42 27. Toffol E, Koponen P, Partonen T. Miscarriage and mental health: results of two population-based studies. *Psychiatry Res*.  
43 2013;205(1-2):151-8.
- 44 28. Kagami M, Maruyama T, Koizumi T, Miyazaki K, Nishikawa-Uchida S, Oda H, Uchida H, Fujisawa D, Ozawa N, Schmidt L,  
45 et al. Psychological adjustment and psychosocial stress among Japanese couples with a history of recurrent pregnancy  
46 loss. *Hum Reprod*. 2012;27(3):787-94.
- 47 29. Mevorach-Zussman N, Bolotin A, Shalev H, Bilenko N, Mazor M, Bashiri A. Anxiety and deterioration of quality of life  
48 factors associated with recurrent miscarriage in an observational study. *J Perinat Med*. 2012;40(5):495-501.
- 49 30. Boynton P. Miscarriage: You don't have to be strong for me. *The Lancet*. 2015;385(9964):222-3.



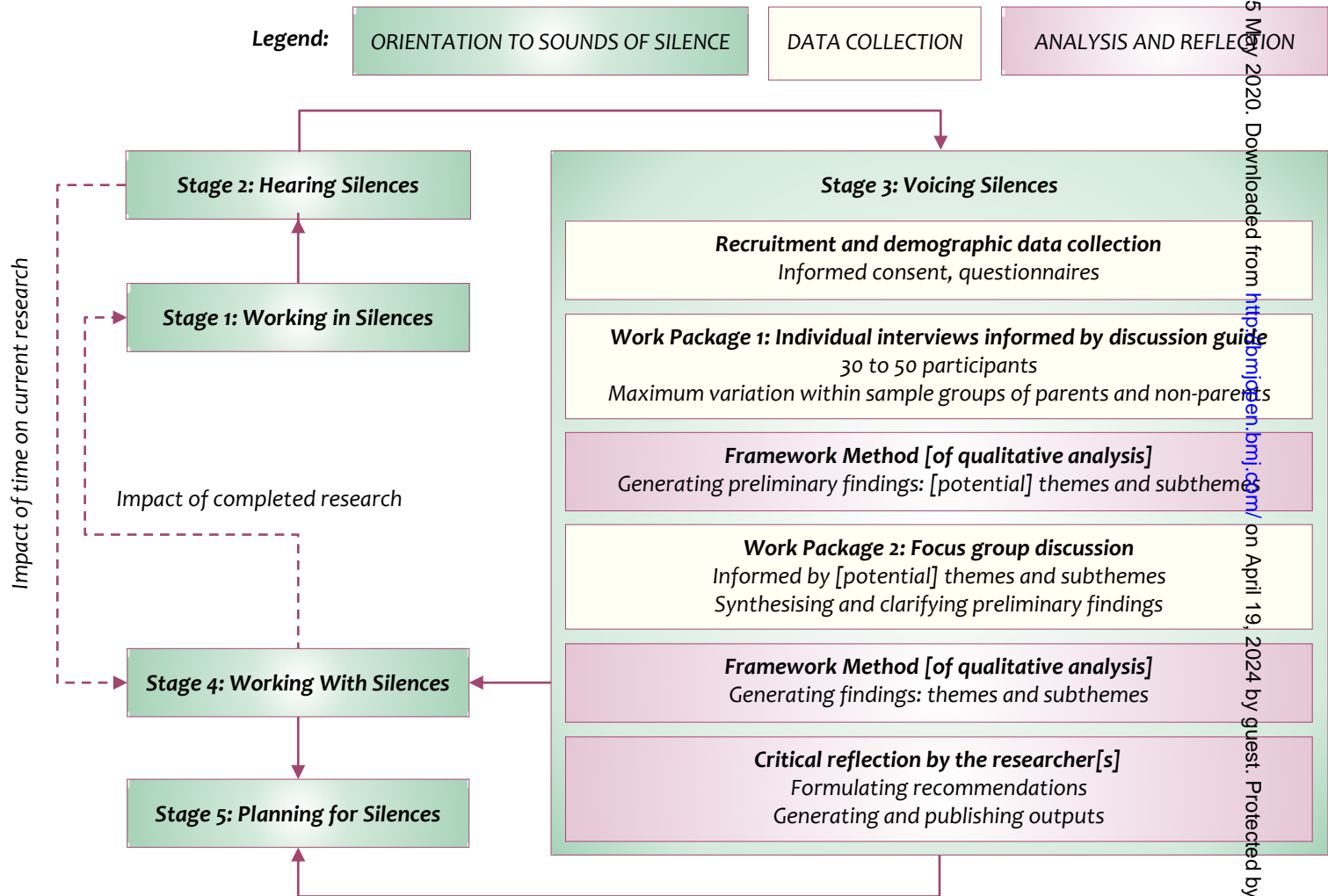
- 1 31. Rowsell E, Jongman G, Kilby M, Kirchmeier R, Orford J. The psychological impact of recurrent miscarriage, and the role  
2 of counselling at a pre-pregnancy counselling clinic. *Journal of Reproductive and Infant Psychology*. 2001;19(1):33-45.
- 3 32. All-Party Parliamentary Group on Baby Loss. The National Bereavement Care Pathway. In: SANDS (Stillbirth and Neonatal  
4 Death Society), ARC (Antenatal Results & Choices), Bliss, Lullaby Trust, Miscarriage Association, Institute of Health  
5 Visiting, et al., editors. A pathway to improve the bereavement care parents in England receive after pregnancy or baby  
6 loss2016.
- 7 33. Donaldson R. Evaluation of the National Bereavement Care Pathway (NBCP). FivewaysNP Ltd; 2019.
- 8 34. Henley A, Schott J. Bereavement Care Report 2010. 2010.
- 9 35. Mackenzie M, Conway E, Hastings A, Munro M, O'Donnell C. Is 'Candidacy' a Useful Concept for Understanding Journeys  
10 through Public Services? A Critical Interpretive Literature Synthesis. *Social Policy & Administration*. 2013;47(7):806-25.
- 11 36. Murphy F, Merrell J. Negotiating the transition: Caring for women through the experience of early miscarriage. *Journal*  
12 *of Clinical Nursing*. 2009;18(11):1583-91.
- 13 37. Rinehart MS, Kiselica MS. Helping men with the trauma of miscarriage. *Psychotherapy*. 2010;47(3):288-95.
- 14 38. Gold KJ. Navigating care after a baby dies: a systematic review of parent experiences with health providers. *Journal of*  
15 *Perinatology: Official Journal of the California Perinatal Association*. 2007;27(4):230-7.
- 16 39. Prior M, Bagness C, Brewin J, Coomarasamy A, Easthope L, Hepworth-Jones B, Hinshaw K, O'Toole E, Orford J, Regan L,  
17 et al. Priorities for research in miscarriage: a priority setting partnership between people affected by miscarriage and  
18 professionals following the James Lind Alliance methodology. *BMJ Open*. 2017;7(8).
- 19 40. Craig M, Tata P, Regan L. Psychiatric morbidity among patients with recurrent miscarriage. *J Psychosom Obstet Gynecol*.  
20 2002;23:157-64.
- 21 41. Musters AM, Taminiu-Bloem EF, Van Den Boogaard E, Van Der Veen F, Goddijn M. Supportive care for women with  
22 unexplained recurrent miscarriage: Patients' perspectives. *Human Reproduction*. 2011;26(4):873-7.
- 23 42. European Society of Human Reproduction and Embryology. Recurrent Pregnancy Loss. ESHRE; 2017.
- 24 43. Atieno OP. An analysis of the strengths and limitation of qualitative and quantitative research paradigms. *Problems of*  
25 *Education in the 21st Century*. 2009;13:13-8.
- 26 44. Marshall C, Rossman GB. *Designing Qualitative Research*. Thousand Oaks, California: Sage Publications; 1999.
- 27 45. Silverman D. *Qualitative Research*. London, England: Sage Publications; 2016.
- 28 46. Watkins DC. Qualitative research: the importance of conducting research that doesn't "count". *Health Promot Pract*.  
29 2012;13(2):153-8.
- 30 47. Berger PL, Luckman T. *The Social Construction of Reality: A Treatise in the Sociology of Knowledge*. New York, United  
31 States: Anchor Books; 1967.
- 32 48. Honderich T. *The Oxford Companion to Philosophy*. Oxford: Oxford University Press; 2005.
- 33 49. Scott J. *A Dictionary of Sociology*. Oxford: Oxford University Press; 2014.
- 34 50. Cannella GS. *Critical Qualitative Research*. 2007.
- 35 51. Harvey L. *Critical Social Research*. Unwim Hyman; 1990.
- 36 52. Serrant-Green L. The sound of silence: a framework for researching sensitive issues or marginalised perspectives in  
37 health. *Journal of Research in Nursing*. 2010;16(4):347-60.
- 38 53. Eshareturi C, Serrant L, Galbraith V, Glynn M. Silence of a scream: application of the Silences Framework to provision of  
39 nurse-led interventions for ex-offenders. *Journal of Research in Nursing*. 2015;20(3):218-31.
- 40 54. Ellard-Gray A, Jeffrey NK, Choubak M, Crann SE. Finding the Hidden Participant. *International Journal of Qualitative*  
41 *Methods*. 2015;14(5).
- 42 55. Association of Early Pregnancy Units. Early Pregnancy Information Centre: AEPUI; 2019 [Available from:  
43 <http://www.aepu.org.uk/>].
- 44 56. Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful Sampling for Qualitative Data  
45 Collection and Analysis in Mixed Method Implementation Research. *Adm Policy Ment Health*. 2015;42(5):533-44.
- 46 57. Diccio-Bloom B, Crabtree BF. The qualitative research interview. *Med Educ*. 2006;40(4):314-21.
- 47 58. Mack NWC, MacQueen K, Guest G, Namey E. *Qualitative Research Methods: A data collector's field guide*. North  
48 Carolina, USA: Family Health International; 2005.

- 1 59. JISC. JISC Online Surveys (formerly BOS). JISC; 2019.
- 2 60. Barrera AZ, Dunn LB, Nichols A, Reardon S, Munoz RF. Getting It 'Right'. *J Empir Res Hum Res Ethics*. 2016;11(4):291-8.
- 3 61. Singer E, Frankel MR. Informed Consent Procedures in Telephone Interviews. *Am Soc Rev*. 1982;47:416-26.
- 4 62. van Hoof M, Widdershoven G. Informed consent in online research: the need for new ways of addressing research
- 5 subjects. *AME Medical Journal*. 2017;2:109-.
- 6 63. Varnhagen CK, Gushta M, Daniels J, Peters TC, Parmar N, Law D, Hirsch R, Takach BS, Johnson T. How informed is online
- 7 informed consent? *Ethics Behav*. 2005;15(1):37-48.
- 8 64. Halej J. Ethics in primary research (focus groups, interviews and surveys). Equality Challenge Unit; 2018.
- 9 65. Lamprell K, Braithwaite J. Patients as story-tellers of healthcare journeys. *Med Humanit*. 2016;42(3):207-9.
- 10 66. McIntosh MJ, Morse JM. Situating and Constructing Diversity in Semi-Structured Interviews. *Glob Qual Nurs Res*. 2015;2.
- 11 67. Gillham B. *Research Interviewing: The Range Of Techniques: A Practical Guide*: Open University Press; 2005. 200 p.
- 12 68. Hermanowicz JC. The Great Interview: 25 Strategies for Studying People in Bed. *Qualitative Sociology*. 2002;25(4).
- 13 69. Drabble L. Conducting qualitative interviews by telephone: Lessons learned from a study of alcohol use among sexual
- 14 minority and heterosexual women. *Qualitative Social Work*. 2016;15(1):118-33.
- 15 70. Farooq MB. Qualitative telephone interviews: strategies for success. 18th Annual Waikato Management School Student
- 16 Research Conference. 2015.
- 17 71. Novick G. Is There a Bias Against Telephone Interviews In Qualitative Research? *Research in Nursing and Health*.
- 18 2008;31(4):391-8.
- 19 72. Trier-Bieniek A. Framing the telephone interview as a participant-centred tool for qualitative research: a methodological
- 20 discussion. *Qualitative Research*. 2012;12(6):630-44.
- 21 73. Vogl S. Telephone Versus Face-to-Face Interviews. *Sociological Methodology*. 2013;43(1):133-77.
- 22 74. Glogowska M, Young P, Lockyer L. Propriety, process and purpose: considerations of the use of the telephone interview
- 23 method in an educational research study. *Higher Education*. 2010;62(1):17-26.
- 24 75. Smith E. Telephone interviewing in healthcare research: a summary of the evidence. *Nurse Researcher*. 2005;12:32-41.
- 25 76. Burgess R. Book Reviews. *Sociology*. 1984;18(1):116-8.
- 26 77. Birt L, Scott S, Cavers D, Campbell C, Walter F. Member Checking: A Tool to Enhance Trustworthiness or Merely a Nod to
- 27 Validation? *Qual Health Res*. 2016.
- 28 78. Klinger L. Occupational Adaptation: Perspectives of People with Traumatic Brain Injury. *Journal of Occupational Science*.
- 29 2005;12(1):9-16.
- 30 79. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for
- 31 interviews and focus groups. *International Journal for Quality in Health Care*. 2007;19(6):349-57.
- 32 80. Barbour RS, Kitzinger J. *Developing Focus Group Research*. London: Sage Publications; 1999.
- 33 81. Breen RL. A Practical Guide to Focus-Group Research. *Journal of Geography in Higher Education*. 2006;30(3):463-75.
- 34 82. Guest G, Namey E, Taylor J, Eley N, McKenna K. Comparing focus groups and individual interviews: findings from a
- 35 randomized study. *International Journal of Social Research Methodology*. 2017;20(6):693-708.
- 36 83. Hollander JA. The Social Contexts of Focus Groups. *Journal of Contemporary Ethnography*. 2016;33(5):602-37.
- 37 84. Kitzinger J. The methodology of focus groups: the importance of interaction between research participants. *Sociology*
- 38 *of Health and Illness*. 1994;16(1):103-21.
- 39 85. Lehoux P, Poland B, Daudelin G. Focus group research and "the patient's view". *Soc Sci Med*. 2006;63(8):2091-104.
- 40 86. Leung F, Savithiri R. Spotlight on focus groups. *Canadian Family Physician*. 2009;55:218-9.
- 41 87. Tausch AP, Menold N. Methodological Aspects of Focus Groups in Health Research: Results of Qualitative Interviews
- 42 With Focus Group Moderators. *Glob Qual Nurs Res*. 2016;3:2333393616630466.
- 43 88. Ritchie J, Lewis J. *Qualitative research practice: a guide for social science students and researchers*. London: Sage; 2003.
- 44 89. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in
- 45 multi-disciplinary health research. *BMC Medical Research Methodology*. 2013;13:117.



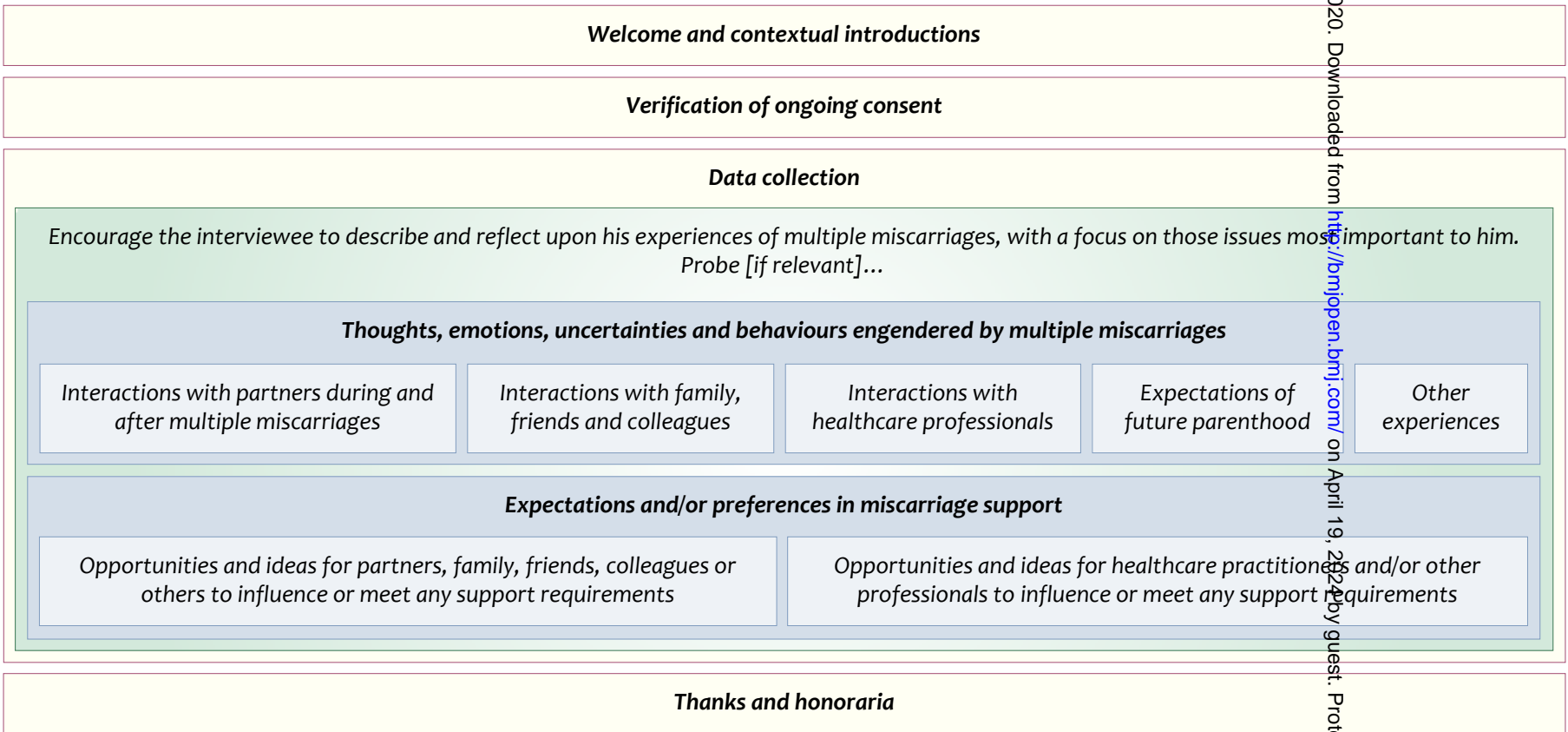
- 1 90. Ritchie J, Spencer L. Qualitative Data Analysis for Applied Policy Research. In: Bryman A, Burgess RG, editors. Analyzing  
2 Qualitative Data: Taylor & Francis Books Ltd; 1994. p. 173-94.
- 3 91. QSR International. NVivo Qualitative Data Analysis Software. 12 ed: QSR International Pty Ltd; 2018.
- 4 92. Hislop J. Analysing Interaction. Introduction to Focus Groups; Oxford: Nuffield Department of Primary Care Health  
5 Sciences, University of Oxford; 2017.
- 6 93. The EQUATOR Network. Enhancing the QUALity and Transparency Of health Research: Minervation Ltd; 2019 [Available  
7 from: <https://www.equator-network.org/>].
- 8 94. Chan AW, Tetzlaff JM, Gotzsche PC, Altman DG, Mann H, Berlin JA, Dickersin K, Hrobjartsson A, Schulz KF, Parulekar WR,  
9 et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ*. 2013;346:e7586.
- 10 95. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human  
11 Use. Guideline for Good Clinical Practice E6 (R1). Current Step 4 version: International Conference on Harmonisation of  
12 Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH); 1996.
- 13 96. Draucker CB, Martsolf DS, Poole C. Developing distress protocols for research on sensitive topics. *Arch Psychiatr Nurs*.  
14 2009;23(5):343-50.
- 15 97. Protection of natural persons with regard to the processing of personal data and on the free movement of such data,  
16 and repealing Directive 95/46/EC: General Data Protection Regulation, (2016).
- 17 98. Data Protection Act 2018. Norwich, England: The Stationery Office (TSO); 2018.
- 18 99. Williams H. Lived Experiences of Miscarriage Birmingham: University of Birmingham; 2019 [Available from:  
19 <https://www.birmingham.ac.uk/research/activity/mds/centres/maternal-health/research/experiences.aspx>].
- 20 100. The Health Foundation. Person-centred care made simple. London: The Health Foundation; 2014.

19-035967 on 15 May 2020. Downloaded from <http://bmjopen.bmj.com/> on April 19, 2024 by guest. Protected by copyright.



**Figure 1: Data Collection and Analysis Embedded within the Silences Framework**

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41



**Figure 2: Indicative Contents of Semi-structured Interviews**

# BMJ Open

## Men Living Through Multiple Miscarriages: Protocol for a Qualitative Exploration of Experiences and Support Requirements

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-035967.R1
Article Type:	Protocol
Date Submitted by the Author:	02-Mar-2020
Complete List of Authors:	Williams, Helen; University of Birmingham, Tommy's National Centre for Miscarriage Research; University of Birmingham, Institute of Clinical Sciences Jones, Laura; University of Birmingham, Institute of Applied Health Research Coomarasamy, Arri; University of Birmingham, Tommy's National Centre for Miscarriage Research; University of Birmingham, Institute of Metabolism and Systems Research Topping, AE; University of Birmingham, Institute of Clinical Sciences; University Hospitals Birmingham NHS Foundation Trust
<b>Primary Subject Heading</b>:	Public health
Secondary Subject Heading:	Qualitative research, Obstetrics and gynaecology
Keywords:	GYNAECOLOGY, PUBLIC HEALTH, QUALITATIVE RESEARCH

SCHOLARONE™  
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1 Men Living Through Multiple Miscarriages:  
2  
3 Protocol for a Qualitative Exploration of Experiences and Support Requirements  
4  
5

---

6  
7  
8  
9 **AUTHORS AND AFFILIATIONS**

10  
11 **Helen M Williams,<sup>1,2\*</sup> Laura L Jones,<sup>1,3</sup> Arri Coomarasamy<sup>1,4</sup> and Annie Topping<sup>1,2,5</sup>**

12  
13  
14 <sup>1</sup>Tommy's National Centre for Miscarriage Research, University of Birmingham, Edgbaston, Birmingham B15 2TT, United  
15  
16 Kingdom

17  
18  
19 <sup>2</sup>Institute of Clinical Sciences, University of Birmingham, Edgbaston, Birmingham B15 2TT, United Kingdom

20  
21  
22 <sup>3</sup>Institute of Applied Health Research, University of Birmingham, Edgbaston, Birmingham B15 2TT, United Kingdom

23  
24  
25 <sup>4</sup>Institute of Metabolism and Systems Research, University of Birmingham, Edgbaston, Birmingham B15 2TT, United Kingdom

26  
27  
28 <sup>5</sup>University Hospitals Birmingham NHS Foundation Trust, Edgbaston, Birmingham B15 2TH, United Kingdom

29  
30  
31  
32 \* Corresponding author, [h.m.williams.1@bham.ac.uk](mailto:h.m.williams.1@bham.ac.uk), 07947 619 960

33  
34  
35  
36  
37 **WORD COUNT, EXCLUDING TITLE PAGE, ABSTRACT, REFERENCES, FIGURES AND TABLES**

38  
39 [3,068 not including acknowledgements etc]

40  
41 [3,262 including acknowledgements etc]

42  
43  
44  
45  
46 **KEYWORDS**

47  
48 Access to health care, families, fathering, fathers, focus groups, framework method, interpersonal relations, lived experience,  
49  
50 masculinity, member synthesis, miscarriage, pregnancy, qualitative research, quality of care, recurrent miscarriage,  
51  
52 reproduction, social marginalisation, social psychology, sounds of silence, telephone interviews.  
53  
54  
55  
56  
57  
58  
59  
60

# Men Living Through Multiple Miscarriages:

## Protocol for a Qualitative Exploration of Experiences and Support Requirements

---

### 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.

#### 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 NHS hospital in England, and from advertisements to be disseminated by miscarriage charities in the United Kingdom.

Telephone interviews supported by a semi-structured discussion guide will be audio-recorded, transcribed and anonymised. The transcriptions and any fieldnotes 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 at a 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 NHS collaborators and miscarriage charities. Outputs are anticipated to inform future policy and practice in the management of multiple miscarriages.

#### Registration

ISRCTN 21828561.

#### STRENGTHS AND LIMITATIONS

- 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 NHS site and advertisements to be disseminated by special interest 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.<sup>1</sup> Many cases go unreported but there is evidence to suggest that more than 200,000 pregnancies end in miscarriage every year in the United Kingdom.<sup>2</sup> Moreover as many as 1 in 20 couples experience more than a single case.<sup>3</sup>

Most miscarriages occur during the first trimester<sup>4</sup> before there is any visible sign of pregnancy and possibly before pregnancy is perceptible by gynaecological ultrasound.<sup>5</sup> Consequently many of these early miscarriages remain unknown and unrecognised. In other cases they remain unspoken or silenced to prevent embarrassment and stigma<sup>6-10</sup> engendered by an outcome that is unplanned and frequently unexplained,<sup>11,12</sup> or because intimate body functions and messy biological symptoms<sup>13</sup> are taboo.<sup>14</sup> As a result the psychosocial effects often remain unacknowledged and unsupported.<sup>8-10,15-26</sup>

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.<sup>22,26</sup> Yet miscarriages<sup>22,24,26-30</sup> or other perinatal loss events<sup>31-37</sup> 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.<sup>38-45</sup>

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

Most of the previous studies adopt quantitative measurements of distress among women.<sup>38-41,43,45</sup> There are fewer qualitative studies,<sup>54</sup> and even fewer to focus on experiences among men.<sup>22,26</sup> Moreover the effects of miscarriages are often conflated with the effects of other perinatal loss events.<sup>31,32,35,55</sup> 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.<sup>26</sup> 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.<sup>56</sup> 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, behaviours, 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<sup>14,57-59</sup> and mediated by uneven power relations between different people.<sup>60,61</sup> Foucault demonstrated the 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.<sup>62-64</sup> More recently Hazen,<sup>6</sup> Martel<sup>55</sup> and other theorists<sup>7,8</sup> 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 upon 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<sup>65</sup> identified sounds of silence<sup>65,66</sup> 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 we could hope via quantitative measurement.<sup>67-70</sup>

<FIGURE 1>

**Figure 1: Data Collection and Analysis Embedded within the Sounds of Silence Framework<sup>65,66</sup>**

In order to overcome the difficulties associated with recruitment among possibly marginalised<sup>71</sup> 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.<sup>72</sup> We seek to recruit men who have lived through two or more pregnancies that were clinically confirmed by ultrasonic data 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 toward obstetric facilities.<sup>50</sup> 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.

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

**Table 1: Inclusion and Exclusion Criteria**

Our previous research<sup>26</sup> and consultations with members of the target population suggest that psychosocial responses to miscarriages may be influenced by perceptions of parenthood.<sup>26</sup> Hence we will recruit purposively<sup>73</sup> 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.<sup>74,75</sup>

## Recruitment

Men will be invited to participate in the study by healthcare practitioners located at the recurrent miscarriage clinic of a large tertiary 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 dedicated webpages of the University of Birmingham. The webpages with information about the study will be advertised via newsletters, tweets and other social media of the University of Birmingham and charitable organisations active in miscarriage research and support. The webpages may also be signposted by those already recruited. We recognise possibilities for chain referral to result in a narrow demographic range so we will aim for broad dissemination through charitable partners to forestall dependency on a snowball effect.<sup>71</sup>

## Informed Consent

Subsequent to introductions and expressions of interest, the research team will liaise with prospective participants by email, telephone and/or 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 data are anonymised and assimilated to the 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.<sup>76-79</sup> Table 2 describes our preparations to facilitate recruitment without undue loss of fidelity to ethical principles of voluntary participation, research integrity and transparency.<sup>79,80</sup>

<b>Issue of Information</b>	<b>Completion of Consent Form</b>	<b>Return of Consent Form</b>
<b>In advance of interview</b>		
Postal delivery	Fill and sign in wet ink by hand	Scan and email as attachment/s
Email with attachment/s	Print, fill and sign in wet ink by hand	<b>OR</b> Photograph and email as attachment/s
	<b>OR</b> Complete, sign and save electronically	<b>OR</b> Pre-paid postal delivery
Secure online survey interface <sup>81</sup>	Complete and sign online	Submit online
<b>At the beginning of audio-recorded interview if methods above are unfeasible</b>		
Read out line-by-line	Respond verbally to each item	Not applicable

**Table 2: Methods of Informed Consent**

## 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 semi-structured interview via telephone within our work package 1. Semi-structured interactions will enable informants to tell us their stories<sup>82</sup> freely enough to yield rich textual data, but without undue diversion to issues beyond the scope of our study objectives.<sup>74</sup> Semi-structured dialogue will also enable investigators to compare different stories more easily than unstructured discussions.<sup>74,83</sup> Interpersonal rapport is essential to an effective

1 qualitative interview, and recent studies refute the historical criticism that it is difficult to establish empathy<sup>84,85</sup> via  
2 telephone. There is further evidence to suggest that telephone communication may facilitate a sense of anonymity, privacy  
3 and freedom, conferring more relational power to interviewees.<sup>86-90</sup> Telephone interviews offer logistic convenience and  
4 feasibility to extend the geographical range of the study population,<sup>86-89,91,92</sup> and they reduce any personal safety risks to the  
5 interviewer.<sup>86,88</sup>  
6  
7

8  
9 Our interviews are anticipated to last up to 60 minutes each. Ongoing consent will be verified and then a semi-structured  
10 discussion guide will support a purposeful conversation with appropriate prompts when required.<sup>93</sup> The interviewer will seek  
11 to explore experiences and support requirements considered to be important by the interviewee. The discussion guide may  
12 be iteratively refined during the period of data collection to enrich data capture, but indicative contents are illustrated in  
13 Figure 2.  
14  
15

16  
17 <FIGURE 2>  
18

### 19 **Figure 2: Indicative Contents of Semi-structured Interviews**

20  
21 All audio-recordings will be transcribed verbatim by specialist transcription suppliers subject to confidentiality agreements to  
22 prevent disclosure to third parties. The study team will review each transcription to ensure accuracy and to anonymise any  
23 personally identifiable data. Then the textual contents will be interpreted and preliminary findings will be presented to study  
24 participants for member synthesis within our work package 2.  
25  
26  
27  
28  
29

### 30 **Data Collection in Work Package 2: Focus Group Discussion**

31  
32 Different voices and silences are audible to different people<sup>65,66</sup> so within our work package 2 we will undertake member  
33 synthesis<sup>65,66,94,95</sup> to enable study participants to elaborate or reconstruct our preliminary interpretations of interview data.<sup>94</sup>  
34  
35 <sup>96</sup> A face-to-face focus group discussion will be facilitated at an accessible location in central England to explore whether or  
36 not stories heard and reported by researchers resonate with perceptions among the sample population. We anticipate a  
37 collective dialogue to elucidate similarities and differences between individual experiences, with additional opportunities to  
38 learn from discursive interactions among the members.<sup>97-102</sup>  
39  
40

41  
42 Invitations will be issued to all study participants by email, telephone, SMS and/or post. Contributions will remain entirely  
43 voluntary and ongoing consent will be verified verbally on the day. After consent is confirmed our preliminary findings in the  
44 form of tentative themes and descriptive or explanatory conclusions will be presented for confirmation or refutation with  
45 new insights and interpretations. Members will be invited to reflect and comment, and to consider any implications for  
46 further research or other action.  
47  
48

49  
50 Our focus group discussion is expected to last for up to 120 minutes, supported by a semi-structured guide if required to  
51 encourage constructive contributions from everybody.<sup>97,98,103,104</sup> The event will be audio-recorded, transcribed verbatim and  
52 anonymised for further analysis.  
53  
54

### 55 **Data Collection in Work Packages 1 and 2: Honoraria and Expenses**

56  
57 All men recruited to the study will be entitled to receive a small honorarium in recognition of the time and effort incurred in  
58 interview participation, and a further honorarium for contribution to focus group discussion. Each of these honoraria will take  
59  
60

1 the form of a £20 digital high street voucher to be issued after data collection. Participants in the focus group discussion will  
2 also be entitled to reclaim reasonable travel expenses.  
3  
4

## 5 **Data Analysis**

6  
7  
8 Our study data collected in interviews and focus group discussion will be examined and interpreted via the framework  
9 method established by Ritchie and Lewis<sup>105</sup> and further described by Gale.<sup>106</sup> The framework method is sufficiently flexible to  
10 suit different theoretical positions and adaptable to inductive or deductive analyses.<sup>106,107</sup> It is also anticipated to facilitate  
11 structured study outputs.<sup>105-107</sup> We will apply the framework method within the sounds of silence framework to enable us to  
12 clearly and concisely communicate the experiences of men who have lived through multiple miscarriages, and to inform the  
13 design and delivery of interventions intended to support them.  
14  
15

16  
17 Transcriptions will be imported into nVivo<sup>108</sup> software to facilitate data management. First they will be familiarised by the  
18 study team, and then re-examined line-by-line to apply inductive paraphrases as descriptive or conceptual codes. Collectively  
19 these codes will represent a comprehensive index to underpin interpreted meanings and to identify patterns such as themes  
20 and subthemes in the data collected.<sup>105,106</sup> The research team will also use field notes to generate analytic memos as  
21 appropriate to inform the analysis.<sup>105</sup> Study data will then be charted into a matrix to map the interpretations by case  
22 participant and by conceptual idea, and to distil important results and recommendations.<sup>105,106,109</sup>  
23  
24

25  
26 Thus we hope for rich and robust interpretations of perceptions perhaps previously unidentified, to newly elucidate thoughts  
27 and behaviours at play in contemporary experiences of multiple miscarriages.<sup>105,107</sup> The knowledge generated by our study  
28 may also help to answer more deductive questions to arise from those with prior and specific interests within the scope of  
29 these issues. Our theoretical orientation additionally upholds a commitment to development beyond original disclosure: we  
30 will continue to collaborate with NHS and charitable partners, to inform the practice of these and other stakeholders in  
31 miscarriage support.  
32  
33  
34  
35  
36  
37

## 38 **PATIENT AND PUBLIC INVOLVEMENT**

39  
40 Our research to date has been enriched through continuous consultation with an advisory panel of men and women with  
41 experiences of multiple miscarriages, other NHS service users, bereavement midwives and patient experience managers at  
42 Birmingham Women's and Children's Hospital, alongside representatives of charitable organisations and peer support forums  
43 active in miscarriage research and support. These stakeholders will remain actively engaged in study oversight throughout  
44 the lifetime of the project, via regular advisory meetings to enable us to voice and work with silences now and in the future.  
45  
46  
47  
48  
49

## 50 **ETHICS AND DISSEMINATION**

### 51 **Regulatory Compliance**

52  
53  
54 Our study protocol version 2.0 dated 19<sup>th</sup> July 2019 has received a favourable opinion from the West Midlands South  
55 Birmingham Research Ethics Committee on behalf of the Health Research Authority of the United Kingdom (reference  
56 16/WM/0423). Any amendments will be authorised in advance of implementation, and recorded in communication with the  
57 research governance team of the University of Birmingham in the role of sponsor, and with regulatory bodies as appropriate.  
58  
59  
60

1 The project is registered (ISRCTN 21828561) and researchers will adhere to recommendations to report transparently and  
2 completely for the benefit of all relevant stakeholders.<sup>110,111</sup>  
3  
4

## 5 **Risk Assessment and Management**

6  
7  
8 Our study investigators and clinicians will maintain up-to-date training in good clinical practice<sup>112</sup> and make every effort to  
9 remain respectful of the autonomy, privacy and dignity of all contributors to the research. The project will collect personal  
10 data and explore subject matter that could possibly engender emotional distress. However the associated risk will be  
11 mitigated and participants safeguarded wherever possible. The wellbeing of participants and researchers will always be  
12 prioritised ahead of the value of the study to generate new knowledge.  
13  
14

### 15 **Emotional Welfare**

16 Prospective contributors will be encouraged to consider the decision carefully, informed by written literature and  
17 verbal discussion to explain that contribution is entirely voluntary. The investigative team will be continuously  
18 vigilant to ongoing consent, and psychosocial support will be signposted as necessary. Indications of emotional  
19 distress will be managed via a pathway adopted and effective in previous studies.<sup>113</sup> Any participant who appears to  
20 be upset will be invited to take time out. The research team will manage any immediate risk and recommend  
21 individuals to liaise with relevant services such as the bereavement support team of Birmingham Women's and  
22 Children's Hospital, and the Miscarriage Association, if appropriate.  
23  
24

### 25 **Data Security**

26 To prevent inadvertent loss or disclosure of personally identifiable or other information, all study data will be  
27 managed to comply robustly with the EU General Data Protection Regulation 2016/679<sup>114</sup> and Data Protection Act  
28 2018.<sup>115</sup> Consent forms, demographic questionnaires, audio-recordings, transcriptions and field notes will be held  
29 securely in the custody of the Chief Investigator for 10 years after first publication of the project findings.  
30  
31  
32  
33  
34  
35  
36

## 37 **Dissemination**

38  
39 Information about the rationale, aims and methods of the study will be available from webpages of the University of  
40 Birmingham throughout the lifetime of the project.<sup>116</sup> The research team will also make the findings of the study available  
41 without any unnecessary delay through a range of scientific and lay media.  
42  
43  
44

### 45 **Scientific Media**

46 Study findings will be reported in the form of a doctoral research thesis, and submitted for publication as academic  
47 manuscripts, and for presentation at national and international conferences. If the academic manuscripts cannot be  
48 issued openly via commercial publishers, they will be made openly available via a dedicated online repository hosted  
49 by the University of Birmingham.  
50  
51

### 52 **Lay Media**

53 In order to ensure the study findings gain maximum impact beyond the academic community, we will liaise with our  
54 NHS and charitable collaborators to communicate the results via meetings, newsletters, webpages, posters and  
55 other relevant events and resources of these organisations.  
56  
57

58 Subsequent to first publication of the findings, we will consider external requests to obtain anonymised study data, subject to  
59 a mutually satisfactory data sharing agreement to establish the rights and responsibilities of each party.  
60



## ACKNOWLEDGMENTS

The authors extend many thanks to members of the patient and public advisory panel dedicated to the study. These members include men and women with experiences of multiple miscarriages, other NHS service users and practitioners, and representatives of Tommy's, the Miscarriage Association and other charitable organisations active in miscarriage research and support.

## AUTHOR CONTRIBUTIONS

AC is the Director of Tommy's National Centre for Miscarriage Research, and Chief Investigator of the study. LLJ and AT guided methodological decisions necessary to design the project, and will oversee implementation. With the support of co-authors, 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.

## FUNDING STATEMENT

This study is partially financially supported by Tommy's National Centre for Miscarriage Research. The funders will take no role in study design, data collection and analysis, decision to publish, or preparation of publications.

## COMPETING INTERESTS STATEMENT

The authors declare no conflicts of interest.

## PARTICIPANT CONSENT

Informed consent will be obtained from all study participants.

## ETHICAL REVIEW

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

## REFERENCES

1. RCOG. The Investigation and Treatment of Couples with Recurrent First-trimester and Second-trimester Miscarriage. In: National Institute for Health and Care Excellence, editor. London: RCOG; 2011.
2. Bottomley C. Epidemiology and aetiology of miscarriage and ectopic pregnancy. In: Jurkovic D, Farquharson RG, editors. Acute Gynaecology and Early Pregnancy. London: RCOG Press; 2011. p. 11-22.
3. Rai R, Regan L. Recurrent miscarriage. The Lancet. 2006;368(9535):601-11.
4. Brigham SA, Conlon C, Farquharson RG. A longitudinal study of pregnancy outcome following idiopathic recurrent miscarriage. Human Reproduction. 1999;14(11):2868-71.
5. Jauniaux E, Johns J, Burton GJ. The role of ultrasound imaging in diagnosing and investigating early pregnancy failure. Ultrasound Obstet Gynecol. 2005;25(6):613-24.

- 1 6. Hazen MA. Silences, perinatal loss, and polyphony. *Journal of Organizational Change Management*. 2006;19(2):237-  
2 49.
- 3 7. Miller SC. The Moral Meanings of Miscarriage. *Journal of Social Philosophy*. 2015;46(1):141-57.
- 4 8. Renner CH, Verdekal S, Brier S, Fallucca G. The meaning of miscarriage to others: Is it an unrecognized loss? *Journal*  
5 *of Personal & Interpersonal Loss*. 2000;5(1):65-76.
- 6 9. Rowlands IJ, Lee C. The silence was deafening: Social and health service support after miscarriage. *Journal of*  
7 *Reproductive and Infant Psychology*. 2010;28(3):274-86.
- 8 10. Wojnar DM, Swanson KM, Adolffson A-S. Confronting the inevitable: A conceptual model of miscarriage for use in  
9 *clinical practice and research*. *Death Studies*. 2011;35(6):536-58.
- 10 11. Garrido-Gimenez C, Alijotas-Reig J. Recurrent miscarriage: causes, evaluation and management. *Postgraduate*  
11 *Medical Journal*. 2015;91:151-62.
- 12 12. Saravelos SH, Li TC. Unexplained recurrent miscarriage: how can we explain it? *Hum Reprod*. 2012;27(7):1882-6.
- 13 13. Miscarriage Association. *Management of miscarriage: your options*. Wakefield: Miscarriage Association; 2016.
- 14 14. Lou S, Frumer M, Schlutter MM, Petersen OB, Vogel I, Nielsen CP. Experiences and expectations in the first trimester  
15 *of pregnancy: a qualitative study*. *Health Expect*. 2017;20(6):1320-9.
- 16 15. Brier N. Understanding and managing the emotional reactions to a miscarriage. *Obstetrics and Gynecology*.  
17 1999;93(1):151-5.
- 18 16. Evans R. Emotional care for women who experience miscarriage. *Nursing Standard*. 2012;26(42):35-41.
- 19 17. Frost M, Condon JT. The psychological sequelae of miscarriage: a critical review of the literature. *Aust N Z J*  
20 *Psychiatry*. 1996;30(1):54-62.
- 21 18. Geller PA, Psaros C, Kornfield SL. Satisfaction with pregnancy loss aftercare: Are women getting what they want?  
22 *Archives of Women's Mental Health*. 2010;13(2):111-24.
- 23 19. Hazen MA. Societal and workplace responses to perinatal loss: Disenfranchised grief or healing connection. *Human*  
24 *Relations*. 2003;56(2):147-66.
- 25 20. Layne LL. Motherhood lost: Cultural dimensions of miscarriage and stillbirth in America. *Women and Health*.  
26 1990;16(3-4):69-98.
- 27 21. Lee C, Slade P. Miscarriage as a traumatic event: A review of the literature and new Implications for intervention.  
28 *Journal of Psychosomatic Research*. 1996;40(3):235-44.
- 29 22. Miller EJ, Temple-Smith MJ, Bilardi JE. 'There was just no-one there to acknowledge that it happened to me as well':  
30 *A qualitative study of male partner's experience of miscarriage*. *PLoS One*. 2019;14(5):e0217395.
- 31 23. Randolph AL, Hruby BT, Sharif S. Counseling Women Who Have Experienced Pregnancy Loss: A Review of the  
32 *Literature*. *Adultspan Journal*. 2015;14(1):2-10.
- 33 24. van den Akker OBA. The psychological and social consequences of miscarriage. *Expert Review of Obstetrics and*  
34 *Gynecology*. 2011;6(3):295-304.
- 35 25. van den Berg MMJ, Dancet EAF, Erlikh T, van der Veen F, Goddijn M, Hajenius PJ. Patient-centered early pregnancy  
36 *care: a systematic review of quantitative and qualitative studies on the perspectives of women and their partners*. *Human*  
37 *Reproduction Update*. 2018;24(1):106-18.
- 38 26. Williams HM, Topping A, Coomarasamy A, Jones LL. Men and Miscarriage: A Systematic Review and Thematic  
39 *Synthesis*. *Qualitative Health Research*. 2019;1049732319870270.
- 40 27. Beutel M, Willner H, Deckardt R, von Rad M, Weiner H. Similarities and differences in couples' grief reactions  
41 *following a miscarriage: results from a longitudinal study*. *J Psychosom Res*. 1996;40(3):245-53.
- 42 28. Brier N. Anxiety After Miscarriage: A Review of the Empirical Literature and Implications for Clinical Practice. *Birth*.  
43 2004;31(2):138-42.
- 44 29. Brier N. Grief following miscarriage: a comprehensive review of the literature. *Journal of Women's Health*.  
45 2008;17(3):451-64.
- 46 30. Radford EJ, Hughes M. Women's experiences of early miscarriage: implications for nursing care. *Journal of Clinical*  
47 *Nursing*. 2015;24(11-12):1457-65.
- 48 31. Due C, Chiarolli S, Riggs DW. The impact of pregnancy loss on men's health and wellbeing: a systematic review. *BMC*  
49 *Pregnancy and Childbirth*. 2017;17(1):380.



- 1 32. Hughes CB, Page-lieberman J. Fathers experiencing a perinatal loss. *Death Studies*. 1989;13(6):537-56.
- 2 33. Kavanaugh K. Gender Differences among Parents Who Experience the Death of an Infant Weighing Less Than 500
- 3 Grams at Birth. *OMEGA - Journal of Death and Dying*. 2016;35(3):281-96.
- 4 34. Obst KL, Due C. Australian men's experiences of support following pregnancy loss: A qualitative study. *Midwifery*.
- 5 2019;70:1-6.
- 6 35. Riggs DW, Due C, Tape N. Australian Heterosexual Men's Experiences of Pregnancy Loss: The Relationships Between
- 7 Grief, Psychological Distress, Stigma, Help-Seeking, and Support. *Omega (Westport)*. 2018;30222818819339.
- 8 36. Weaver-Hightower MB. *Waltzing Matilda: An Autoethnography of a Father's Stillbirth*. *Journal of Contemporary*
- 9 *Ethnography*. 2012;41(4):462-91.
- 10 37. Weaver-Hightower MB. *Losing Thomas & Ella: A Father's Story (A Research Comic)*. *J Med Humanit*. 2017;38(3):215-
- 11 30.
- 12 38. Boynton P. Miscarriage: You don't have to be strong for me. *The Lancet*. 2015;385(9964):222-3.
- 13 39. Craig M, Tata P, Regan L. Psychiatric morbidity among patients with recurrent miscarriage. *J Psychosom Obstet*
- 14 *Gynecol*. 2002;23:157-64.
- 15 40. Kagami M, Maruyama T, Koizumi T, Miyazaki K, Nishikawa-Uchida S, Oda H, Uchida H, Fujisawa D, Ozawa N, Schmidt
- 16 L, et al. Psychological adjustment and psychosocial stress among Japanese couples with a history of recurrent pregnancy loss.
- 17 *Hum Reprod*. 2012;27(3):787-94.
- 18 41. Mevorach-Zussman N, Bolotin A, Shalev H, Bilenko N, Mazor M, Bashiri A. Anxiety and deterioration of quality of life
- 19 factors associated with recurrent miscarriage in an observational study. *J Perinat Med*. 2012;40(5):495-501.
- 20 42. Ockhuijsen HDL, Boivin J, van den Hoogen A, Macklon NS. Coping after recurrent miscarriage: uncertainty and
- 21 bracing for the worst. *Journal of Family Planning and Reproductive Health Care*. 2013;39(4):250-6.
- 22 43. Rowsell E, Jongman G, Kilby M, Kirchmeier R, Orford J. The psychological impact of recurrent miscarriage, and the
- 23 role of counselling at a pre-pregnancy counselling clinic. *Journal of Reproductive and Infant Psychology*. 2001;19(1):33-45.
- 24 44. Serrano F, Lima ML. Recurrent miscarriage: Psychological and relational consequences for couples. *Psychology and*
- 25 *Psychotherapy: Theory, Research and Practice*. 2006;79(4):585-94.
- 26 45. Toffol E, Koponen P, Partonen T. Miscarriage and mental health: results of two population-based studies. *Psychiatry*
- 27 *Res*. 2013;205(1-2):151-8.
- 28 46. All-Party Parliamentary Group on Baby Loss. *The National Bereavement Care Pathway*. In: SANDS (Stillbirth and
- 29 Neonatal Death Society), ARC (Antenatal Results & Choices), Bliss, Lullaby Trust, Miscarriage Association, Institute of Health
- 30 Visiting, et al., editors. *A pathway to improve the bereavement care parents in England receive after pregnancy or baby*
- 31 *loss2016*.
- 32 47. Donaldson R. *Evaluation of the National Bereavement Care Pathway (NBCP)*. FivewaysNP Ltd; 2019.
- 33 48. Henley A, Schott J. *Bereavement Care Report 2010*. 2010.
- 34 49. Mackenzie M, Conway E, Hastings A, Munro M, O'Donnell C. Is 'Candidacy' a Useful Concept for Understanding
- 35 *Journeys through Public Services? A Critical Interpretive Literature Synthesis*. *Social Policy & Administration*. 2013;47(7):806-
- 36 25.
- 37 50. Murphy F, Merrell J. Negotiating the transition: Caring for women through the experience of early miscarriage.
- 38 *Journal of Clinical Nursing*. 2009;18(11):1583-91.
- 39 51. Rinehart MS, Kiselica MS. Helping men with the trauma of miscarriage. *Psychotherapy*. 2010;47(3):288-95.
- 40 52. Gold KJ. Navigating care after a baby dies: a systematic review of parent experiences with health providers. *Journal*
- 41 *of Perinatology: Official Journal of the California Perinatal Association*. 2007;27(4):230-7.
- 42 53. Prior M, Bagness C, Brewin J, Coomarasamy A, Easthope L, Hepworth-Jones B, Hinshaw K, O'Toole E, Orford J,
- 43 Regan L, et al. Priorities for research in miscarriage: a priority setting partnership between people affected by miscarriage and
- 44 professionals following the James Lind Alliance methodology. *BMJ Open*. 2017;7(8).
- 45 54. Musters AM, Taminiau-Bloem EF, Van Den Boogaard E, Van Der Veen F, Goddijn M. Supportive care for women with
- 46 unexplained recurrent miscarriage: Patients' perspectives. *Human Reproduction*. 2011;26(4):873-7.
- 47 55. Martel SL. Biopower and Reproductive Loss. *Cultural Studies*. 2013;28(2):327-45.
- 48 56. European Society of Human Reproduction and Embryology. *Recurrent Pregnancy Loss*. ESHRE; 2017.

- 1 57. Berger PL, Luckman T. *The Social Construction of Reality: A Treatise in the Sociology of Knowledge*. New York,  
2 United States: Anchor Books; 1967.
- 3 58. Honderich T. *The Oxford Companion to Philosophy*. Oxford: Oxford University Press; 2005.
- 4 59. Scott J. *A Dictionary of Sociology*. Oxford: Oxford University Press; 2014.
- 5 60. Cannella GS. *Critical Qualitative Research*. 2007.
- 6 61. Harvey L. *Critical Social Research*. Unwim Hyman; 1990.
- 7 62. Bindeman SL. Foucault on Silence as Discourse. In: Bindeman S, editor. *Silence in Philosophy, Literature, and Art*:  
8 BRILL; 2017. p. 143–6.
- 9 63. Foucault M. *The Archeology of Knowledge*. London, England: Tavistock Publications; 1972.
- 10 64. Foucault M. *The History of Sexuality: 1: The Will to Knowledge*: Penguin Books; 1976, 1988.
- 11 65. Serrant-Green L. The sound of silence: a framework for researching sensitive issues or marginalised perspectives in  
12 health. *Journal of Research in Nursing*. 2010;16(4):347-60.
- 13 66. Eshareturi C, Serrant L, Galbraith V, Glynn M. Silence of a scream: application of the Silences Framework to provision  
14 of nurse-led interventions for ex-offenders. *Journal of Research in Nursing*. 2015;20(3):218-31.
- 15 67. Atieno OP. An analysis of the strengths and limitation of qualitative and quantitative research paradigms. *Problems*  
16 *of Education in the 21st Century*. 2009;13:13-8.
- 17 68. Marshall C, Rossman GB. *Designing Qualitative Research*. Thousand Oaks, California: Sage Publications; 1999.
- 18 69. Silverman D. *Qualitative Research*. London, England: Sage Publications; 2016.
- 19 70. Watkins DC. Qualitative research: the importance of conducting research that doesn't "count". *Health Promot Pract*.  
20 2012;13(2):153-8.
- 21 71. Ellard-Gray A, Jeffrey NK, Choubak M, Crann SE. Finding the Hidden Participant. *International Journal of Qualitative*  
22 *Methods*. 2015;14(5).
- 23 72. Association of Early Pregnancy Units. Early Pregnancy Information Centre: AEP; 2019 [Available from:  
24 <http://www.aepu.org.uk/>].
- 25 73. Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful Sampling for Qualitative Data  
26 Collection and Analysis in Mixed Method Implementation Research. *Adm Policy Ment Health*. 2015;42(5):533-44.
- 27 74. Diccico-Bloom B, Crabtree BF. The qualitative research interview. *Med Educ*. 2006;40(4):314-21.
- 28 75. Mack NWC, MacQueen K, Guest G, Namey E. *Qualitative Research Methods: A data collector's field guide*. North  
29 Carolina, USA: Family Health International; 2005.
- 30 76. Barrera AZ, Dunn LB, Nichols A, Reardon S, Munoz RF. Getting It 'Right'. *J Empir Res Hum Res Ethics*. 2016;11(4):291-8.
- 31 77. Singer E, Frankel MR. Informed Consent Procedures in Telephone Interviews. *Am Soc Rev*. 1982;47:416-26.
- 32 78. van Hoof M, Widdershoven G. Informed consent in online research: the need for new ways of addressing research  
33 subjects. *AME Medical Journal*. 2017;2:109-.
- 34 79. Varnhagen CK, Gushta M, Daniels J, Peters TC, Parmar N, Law D, Hirsch R, Takach BS, Johnson T. How informed is  
35 online informed consent? *Ethics Behav*. 2005;15(1):37-48.
- 36 80. Halej J. *Ethics in primary research (focus groups, interviews and surveys)*. Equality Challenge Unit; 2018.
- 37 81. JISC. *JISC Online Surveys (formerly BOS)*. JISC; 2019.
- 38 82. Lamprell K, Braithwaite J. Patients as story-tellers of healthcare journeys. *Med Humanit*. 2016;42(3):207-9.
- 39 83. McIntosh MJ, Morse JM. Situating and Constructing Diversity in Semi-Structured Interviews. *Glob Qual Nurs Res*.  
40 2015;2.
- 41 84. Gillham B. *Research Interviewing: The Range Of Techniques: A Practical Guide*: Open University Press; 2005. 200 p.
- 42 85. Hermanowicz JC. The Great Interview: 25 Strategies for Studying People in Bed. *Qualitative Sociology*. 2002;25(4).
- 43 86. Drabble L. Conducting qualitative interviews by telephone: Lessons learned from a study of alcohol use among  
44 sexual minority and heterosexual women. *Qualitative Social Work*. 2016;15(1):118–33.
- 45 87. Farooq MB. *Qualitative telephone interviews: strategies for success*. 18th Annual Waikato Management School  
46 Student Research Conference. 2015.

- 1 88. Novick G. Is There a Bias Against Telephone Interviews In Qualitative Research? *Research in Nursing and Health*.  
2 2008;31(4):391–8.
- 3 89. Trier-Bieniek A. Framing the telephone interview as a participant-centred tool for qualitative research: a  
4 methodological discussion. *Qualitative Research*. 2012;12(6):630-44.
- 5 90. Vogl S. Telephone Versus Face-to-Face Interviews. *Sociological Methodology*. 2013;43(1):133-77.
- 6 91. Glogowska M, Young P, Lockyer L. Propriety, process and purpose: considerations of the use of the telephone  
7 interview method in an educational research study. *Higher Education*. 2010;62(1):17-26.
- 8 92. Smith E. Telephone interviewing in healthcare research: a summary of the evidence. *Nurse Researcher*. 2005;12:32-41.
- 9 93. Burgess R. Book Reviews. *Sociology*. 1984;18(1):116-8.
- 10 94. Birt L, Scott S, Cavers D, Campbell C, Walter F. Member Checking: A Tool to Enhance Trustworthiness or Merely a  
11 Nod to Validation? *Qual Health Res*. 2016.
- 12 95. Klinger L. Occupational Adaptation: Perspectives of People with Traumatic Brain Injury. *Journal of Occupational  
13 Science*. 2005;12(1):9-16.
- 14 96. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for  
15 interviews and focus groups. *International Journal for Quality in Health Care*. 2007;19(6):349–57.
- 16 97. Barbour RS, Kitzinger J. *Developing Focus Group Research*. London: Sage Publications; 1999.
- 17 98. Breen RL. A Practical Guide to Focus-Group Research. *Journal of Geography in Higher Education*. 2006;30(3):463-75.
- 18 99. Guest G, Namey E, Taylor J, Eley N, McKenna K. Comparing focus groups and individual interviews: findings from a  
19 randomized study. *International Journal of Social Research Methodology*. 2017;20(6):693-708.
- 20 100. Hollander JA. The Social Contexts of Focus Groups. *Journal of Contemporary Ethnography*. 2016;33(5):602-37.
- 21 101. Kitzinger J. The methodology of focus groups: the importance of interaction between research participants.  
22 *Sociology of Health and Illness*. 1994;16(1):103-21.
- 23 102. Lehoux P, Poland B, Daudelin G. Focus group research and "the patient's view". *Soc Sci Med*. 2006;63(8):2091-104.
- 24 103. Leung F, Savithiri R. Spotlight on focus groups. *Canadian Family Physician*. 2009;55:218-9.
- 25 104. Tausch AP, Menold N. Methodological Aspects of Focus Groups in Health Research: Results of Qualitative Interviews  
26 With Focus Group Moderators. *Glob Qual Nurs Res*. 2016;3:2333393616630466.
- 27 105. Ritchie J, Lewis J. *Qualitative research practice: a guide for social science students and researchers*. London: Sage;  
28 2003.
- 29 106. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data  
30 in multi-disciplinary health research. *BMC Medical Research Methodology*. 2013;13:117.
- 31 107. Ritchie J, Spencer L. *Qualitative Data Analysis for Applied Policy Research*. In: Bryman A, Burgess RG, editors.  
32 *Analyzing Qualitative Data: Taylor & Francis Books Ltd; 1994. p. 173-94.*
- 33 108. QSR International. *NVivo Qualitative Data Analysis Software*. 12 ed: QSR International Pty Ltd; 2018.
- 34 109. Hislop J. *Analysing Interaction. Introduction to Focus Groups*; Oxford: Nuffield Department of Primary Care Health  
35 Sciences, University of Oxford; 2017.
- 36 110. The EQUATOR Network. *Enhancing the QUALity and Transparency Of health Research*: Minervation Ltd; 2019  
37 [Available from: <https://www.equator-network.org/>].
- 38 111. Chan AW, Tetzlaff JM, Gotzsche PC, Altman DG, Mann H, Berlin JA, Dickersin K, Hrobjartsson A, Schulz KF, Parulekar  
39 WR, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ*. 2013;346:e7586.
- 40 112. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for  
41 Human Use. *Guideline for Good Clinical Practice E6 (R1)*. Current Step 4 version: International Conference on Harmonisation of  
42 Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH); 1996.
- 43 113. Draucker CB, Martsof DS, Poole C. Developing distress protocols for research on sensitive topics. *Arch Psychiatr  
44 Nurs*. 2009;23(5):343-50.
- 45 114. Protection of natural persons with regard to the processing of personal data and on the free movement of such  
46 data, and repealing Directive 95/46/EC: *General Data Protection Regulation*, (2016).
- 47 115. *Data Protection Act 2018*. Norwich, England: The Stationery Office (TSO); 2018.

1 116. Williams H. Lived Experiences of Miscarriage Birmingham: University of Birmingham; 2019 [Available from:  
2 <https://www.birmingham.ac.uk/research/activity/mds/centres/maternal-health/research/experiences.aspx>].  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

For peer review only

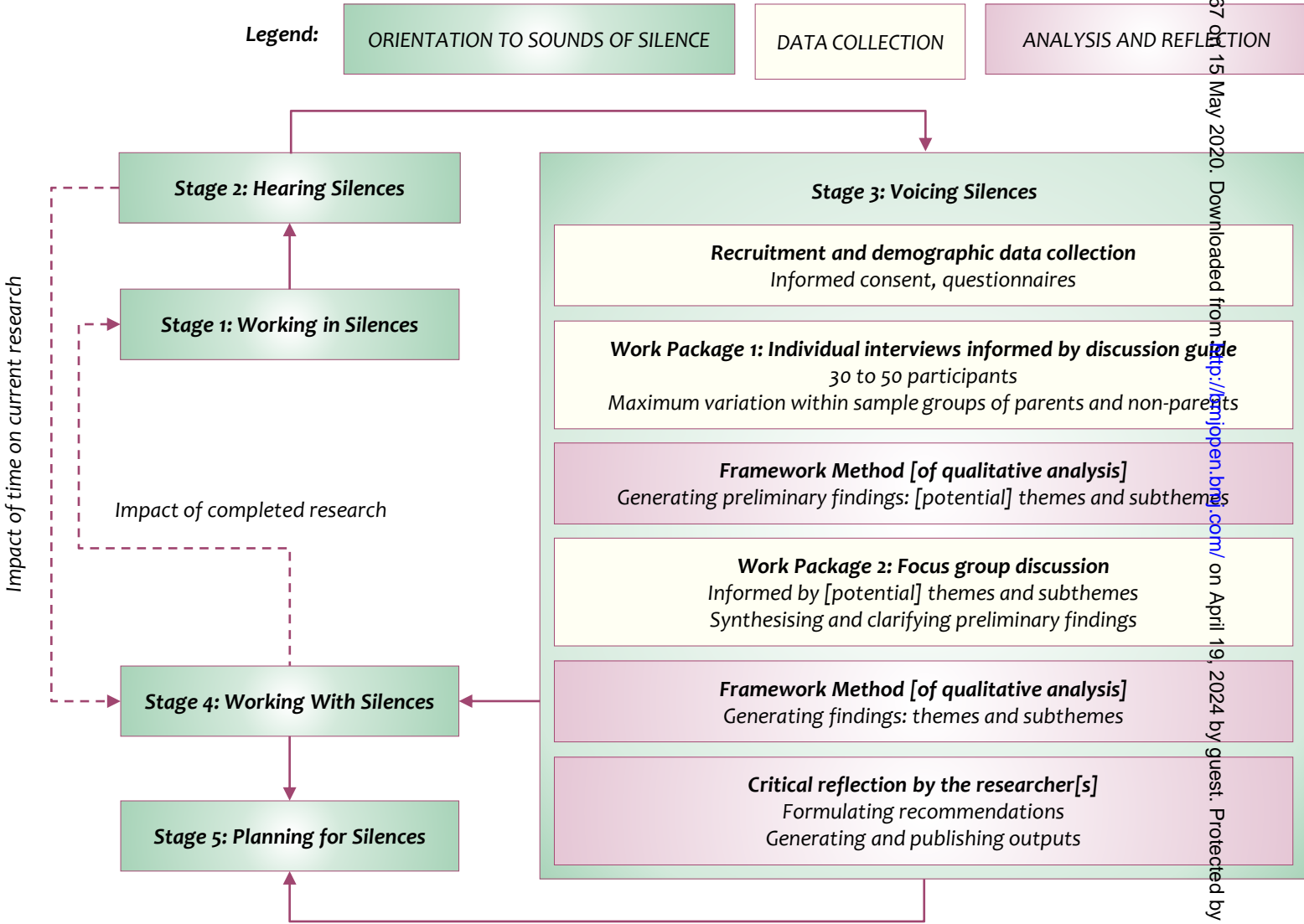
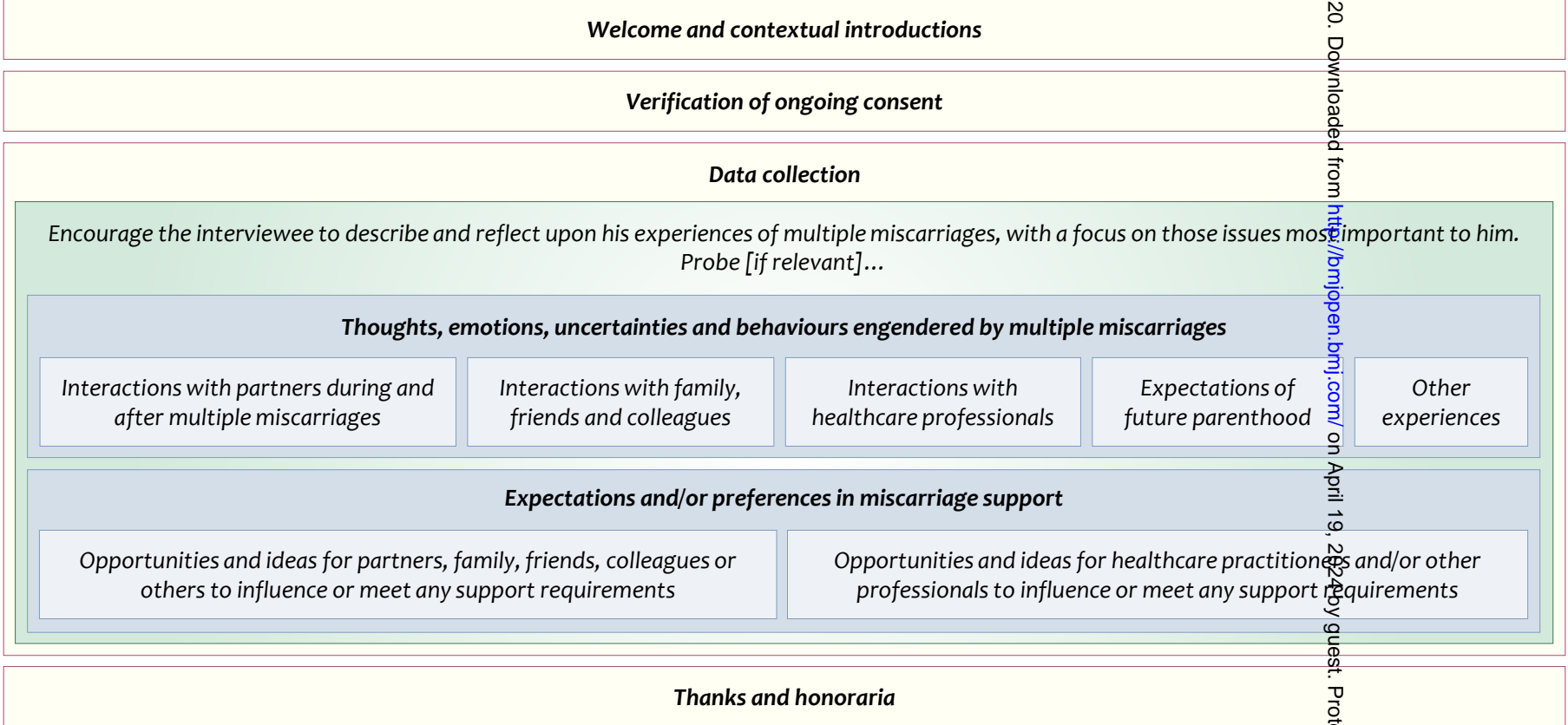


Figure 1: Data Collection and Analysis Embedded within the Sounds of Silence Framework<sup>65,66</sup>

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41

19-035967 on 15 May 2020. Downloaded from <http://bmjopen.bmj.com/> on April 19, 2024 by guest. Protected by copyright.

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41



**Figure 2: Indicative Contents of Semi-structured Interviews**