FGM Sister Study

Female Genital Mutilation: a qualitative study exploring the views of survivors, male partners and healthcare professionals on the timing of deinfibulation surgery (the FGM Sister Study)

This protocol has regard for HRA guidance and order of content

Signature Page

Full Study Title

Female Genital Mutilation: a qualitative study exploring the views of survivors, male partners and healthcare professionals on the timing of deinfibulation surgery (the FGM Sister Study)

Short Study Title

FGM Sister Study

Study Protocol

Version 1.0	11th June 2018
Version 2.0	10th April 2019

Study Reference Numbers

IRAS Number:	235256
Sponsor Number:	University of Birmingham 17-188
REC Number:	18/NW/0498
ISRCTN:	14710507
Funder Number:	National Institute for Health Research (HTA 16/78/04)

Signatures

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

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

The undersigned also agree to make the findings of the study freely available through publication or other dissemination tools without any unnecessary delay, and confirm that an honest, accurate and transparent account of the study will be given, with explanation for any discrepancies from the study as planned in this protocol.

Chief Investigator:

Signature:  Date: 10/04/2019

Name [please print]: Dr Laura Jones

Sponsor statement

Where the University of Birmingham takes on the sponsor role for protocol development oversight, the signing of the IRAS form by the sponsor will serve as confirmation of approval of this protocol.

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Key Study Information

Study Contacts

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Committees	**Study Management Group (SMG)** Chair: Dr Laura Jones Other members: Professor Julie Taylor, Professor Kate Jolly, Dr Pallavi Latthe, Mrs Emma Danks, Mrs Alison Byrne, Mrs Meg Fassam-Wright, Mrs Hibo Wardere, Dr Benjamin Costello, and Dr Joanne Clarke **Study Steering Group (SSG)** Chair: Professor Charlotte Clarke Other members: Professor Hazel Barrett, Dr Catrin Evans, Ms Juliet Albert, Ms Rachael Oluyemi, Mr Toks Okeniyi, Mrs Sylla Mama Barry, Mrs Emma Mills, Dr Laura Jones, Professor Julie Taylor. Members in attendance Mrs Emma Danks, Dr Benjamin Costello, and Dr Joanne Clarke. **Patient and Public Advisory Group** Co-Chairs: Dr Laura Jones & Mrs Hibo Wardere Other members: Four members (names not provided due to the sensitive nature of the research and their wish to remain anonymous).

Study Summary

Study Title	Female Genital Mutilation: a qualitative study exploring the views of survivors, male partners and healthcare professionals on the timing of deinfibulation surgery (the FGM Sister Study)
Short title	FGM Sister Study
Study Design	Qualitative research study informed by the Sound of Silences conceptual framework involving two key work packages.
Study Participants	**Work package 1** Women who are female genital mutilation/cutting (FGM/C) survivors (type 3 where this can be ascertained) and male partners of FGM/C-survivors who are able and willing to give informed consent, live in large ethnically diverse cities in England (Birmingham, London and Manchester), aged 18 years or over, and who speak English, Somali, Arabic and/or French. Healthcare professionals (HCPs) who are able and willing to give informed consent, working (or having worked within the last 5 years) in the UK in high and low FGM/C prevalence settings and who provide care to FGM/C-survivors including (but not limited to) GPs, practice nurses, midwives, obstetrics and gynaecology clinicians, genitourinary clinicians and sexual health specialists. **Work package 2** Women who are FGM/C survivors (type 3 where this can be ascertained) and male partners of FGM/C-survivors who are able and willing to give informed consent, live in large ethnically diverse cities in England (Birmingham, London and Manchester), aged 18 years or over, and who speak fluent English. Stakeholders including health and social care professionals, policy makers, FGM/C specialist researchers/academics, health economists, commissioners, representatives from third sector organisations (e.g. Charities and Advocacy groups) currently or recently involved (within the last 5 years) in delivery of care to FGM/C-survivors and their families in the UK, willing and able to give informed consent, over the age of 18 years and who speak fluent English.
Planned Size of Sample [if applicable]	**Work package 1** (total n up to 110) We will seek to recruit: • up to 50 women who are FGM/C-survivors • up to 10 male partners • up to 50 HCPs **Work package 2** (total n up to 60) We will seek to recruit: • 20-25 FGM/C-survivors for the community engagement event

	• 30-35 stakeholders for the national stakeholder event (please note that numbers will remain flexible to ensure that we collect sufficiently rich data to answer the research questions and achieve core analytic saturation)
Follow Up Duration [if applicable]	Not applicable
Planned Study Period	1st May 2018 to 30th April 2020
Research Question or Aim[s]	**Overall study aim** To explore and understand FGM/C-survivors', their male partners' and healthcare professionals' preferences for the timing of deinfibulation and their views on how NHS services can best be delivered to meet the needs of FGM/C-survivors and their families. This overarching aim will be addressed in two work packages (WP). **Work package 1** **Aim**: to qualitatively explore and understand the timing preferences for deinfibulation and how NHS FGM/C services could be improved for type 3 FGM/C-survivors (WP1a), their male partners (WP1b), and HCPs (WP1c). **Objectives** a. to explore knowledge, awareness and understanding of FGM/C and deinfibulation (WP1a,b,c) b. to elicit views on preferences for the timing of deinfibulation and the rationale for these (WP1a,b,c) c. to explore perspectives on the decision making process around deinfibulation (WP1a,b) d. to explore knowledge, awareness, and experiences of FGM/C services and support (WP1,a,b,c) e. to understand the enablers, motivators and barriers to FGM/C care seeking behaviours (WP1,a,b) f. to explore how HCPs describe, explain and reason about their care provision for FGM/C-survivors and their families (WP1c) g. to understand how FGM/C care services could be improved to best meet the needs of FGM/C-survivors, their families and HCPs who support them in their local context (WP1,a,b,c) **Work package 2** **Aim**: to use established techniques to synthesise the qualitative research findings, inform best practice and policy recommendations around the timing of deinfibulation and FGM/C care provision, and identify future actions. **Objectives** a. to explore views and reflections on the trustworthiness of our interpretation of the data and the conclusions drawn (WP2a,b)

	b. to establish if there is consensus about the optimal timing of deinfibulation (WP2a,b) c. to identify the key recommendations to inform NHS FGM/C care provision (WP2a,b) d. to explore the facilitators and barriers to implementation of changes to NHS FGM/C care provision (WP2b) e. to explore views on the requirements for future FGM/C research (e.g. RCT) (WP2b)
Key Words	*Female Circumcision, Female Genital Mutilation, Female Genital Cutting, Healthcare Professional, *Men, *Qualitative Research. *Interview, *Focus Group, Community Engagement, Stakeholder Event, Sound of Silences [*MeSH terms]

Funding and Support in Kind

Organisation	Funding or Other Support
University of Birmingham	Research sponsorship, and financial contributions to researcher salary and support costs [e.g. IT services, telephone, printing, desk space]
National Institute for Health Research	Provision of research related costs
FGM National Centre, Barnardo's Children's Charity	Research support costs [e.g. IT services, telephone, printing, desk space]

Roles of Study Sponsor and Funder

The University of Birmingham, as the sponsor, will assume overall responsibility for initiation and management of the study, and will control final decisions regarding all aspects of the study. NIHR, as the funder, will contribute financial support and facilitate dissemination of the results.

Roles and Responsibilities of Study Management Committees/Groups & Individuals

STUDY MANAGEMENT GROUP

A Study Management Group (SMG) involving all co-applicants and appointed research staff (where available) will oversee the study and will meet every 3 to 4 months (up to a maximum of 8 times). The CI (LJ) will meet with co-applicants KJ and/or JT (mentors) on a monthly basis to discuss study progress. LJ will also meet with project research staff every two weeks (as necessary).

STUDY STEERING GROUP

A multidisciplinary Study Steering group (SSG) has been convened to provide independent oversight and overall supervision of the proposed qualitative research study. The SSG will provide advice to the investigators on all aspects of the study and will agree the study protocol and any protocol amendments for the duration of the project. The SSG will be chaired by Professor Charlotte Clark, Head of the School of Health in Social Science and International Dean for the College of Humanities and Social Science at the University of Edinburgh. A further six independent members including FGM academics, FGM specialist clinicians, an FGM/C-survivor and FGM/C third sector organisation representatives, form the SSG. The SSG will meet up to four times during the project.

PATIENT AND PUBLIC INVOLVEMENT ADVISORY PANEL

We have established a PPI advisory panel that is co-chaired by the CI (LJ) and PPI lead co-applicant (HW). The panel consists of four PPI representatives each of whom are type 3 FGM-C survivors. Some have undergone deinfibulation whilst others have not. The role and expectations of PPI advisory members have been clearly outlined already and will be formalised (e.g. by providing role descriptors, establishing terms of reference) at the start of the study. It is anticipated that we will run 4 half day PPI advisory group meetings across the 24 month study. These will be co-chaired (where possible) by LJ and HW with the support of ED.

Protocol Contributors

The CI (LJ), with the wider support of the co-investigators conceived and designed the study and drafted the original study protocol. The study protocol has undergone multiple rounds of expert peer-review as part of the funding process. All collaborators have critically reviewed version 1.0 and actively contribution to revisions throughout the process. The Patient and Public Advisory Group have commented on version 1.0.

Keywords

*Female Circumcision, Female Genital Mutilation, Female Genital Cutting, Healthcare Professional, *Men, *Qualitative Research. *Interview, *Focus Group, Community Engagement, Stakeholder Event, Sound of Silences

[*MESH terms]

Study Flow Chart

16/78/04 Female Genital Mutilation: a qualitative study exploring survivors' and healthcare professionals' views on the timing of deinfibulation surgery (FGM Sister Study)																										
Work Package (WP) / Study Phase		Work Package 1/Phase 1																	Work Package 2/Phase 2							
		Work Package 1/Phase 1																								
																			Work Package 2/Phase 2							
Project Month	-1	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	
Calendar Month	Apr-18	May-18	Jun-18	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18	Jan-19	Feb-19	Mar-19	Apr-19	May-19	Jun-19	Jul-19	Aug-19	Sep-19	Oct-19	Nov-19	Dec-19	Jan-20	Feb-20	Mar-20	Apr-20	
Milestones/Description																										
1	Submission of application for HRA approval via IRAS	X																								
2	Study set up: HRA & Governance Approvals; Staff Appointments; Network Building; Identification and training of recruiters, interpreters and translators		X	X	X																					
3	Submission of study protocol for publication				X						X															
4	WP1a Recruit and undertake qualitative data collection with female genital mutilation/cutting survivors, initial analysis				X	X	X	X	X	X	X	X	X	X	X	X	X	X	X							
5	WP1b Recruit and undertake qualitative data collection with male partners of female genital mutilation/cutting survivors, initial analysis				X	X	X	X	X	X	X	X	X	X	X	X	X	X	X							
6	WP1c Recruit and undertake qualitative data collection with healthcare professionals involved in the care of female genital mutilation/cutting survivors, initial analysis				X	X	X	X	X	X	X	X	X	X	X	X	X	X	X							
7	WP1 Intensive Analysis															X	X		X	X						
8	Preparation for WP2																	X	X	X						
9	WP2a Community Engagement Event																			X	X					
	Delivery of written report of WP2a Community Engagement Event																				X	X				
10	WP2b National Stakeholder Event																					X	X			
	Delivery of written report of WP2b National Stakeholder Event																						X	X		
11	Publication writing and dissemination			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
12	Study Management Group (SMG) meetings	X		X			X			X			X				X				X				X	
13	Study Steering Group (SSG) meetings		X							X									X						X	
14	Patient and Public Involvement (PPI) meetings	X				X													X	X					X	
15	NIHR Reports/ Monograph Writing						X						X						X			X	X	X	X	

STUDY PROTOCOL

Female Genital Mutilation: a qualitative study exploring the views of survivors, male partners and healthcare professionals on the timing of deinfibulation surgery (the FGM Sister Study)

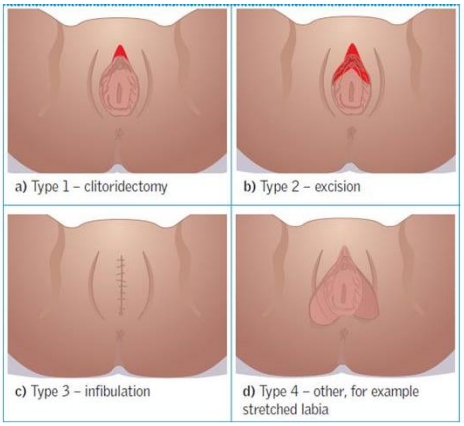
1 Background and Rationale

1.1 Classification of FGM/C

FGM/C involves the partial or complete removal of, or injury to, the external female genitalia for non-medical reasons(1). The WHO/UNICEF/UNFPA joint statement has classified FGM/C into four main types (types 1-4; Figure 1), with a further seven sub-types (types 1a,b; 2a-c; 3a,b) identified to capture more closely the variation in practices(2, 3). Generally, the extent of genital tissue cut increases from type 1 to type 3, with type 3 (infibulation) being the most extensive and often requiring surgical intervention (deinfibulation)(1).

1.2 Prevalence of FGM/C

The practice of FGM/C has been performed for millennia(4) and continues to be prevalent in Sub-Saharan Africa, Asia and the Middle East(5). FGM/C is an increasingly global issue owing to international migration(6). An estimated 200 million women and girls live with FGM/C globally[12] and this is expected to rise significantly in the next 15 years based on current population growth estimates(6). Type 3 FGM/C is experienced by about 10% of all affected women and is most likely to occur in Somalia, northern Sudan and Djibouti[13]. In the UK, FGM/C is increasingly identified amongst migrants from FGM/C-affected countries, with 137,000 women and girls currently living with the consequences[14]. Since 2008, FGM/C-survivors account for up to 1.5% of all women giving birth in England and Wales(7). Of these, 60% were born in countries where type 3 FGM/C is almost universally practiced(7). Between 1996 and 2010, 144,000 girls were born in England and Wales to mothers from FGM/C-affected countries(7).



Type 1: Partial or total removal of the clitoris and/or the prepuce (**clitoridectomy**)

Type 2: Partial or total removal of the clitoris and the labia minora, with or without excision of the labia majora (**excision**)

Type 3: Narrowing of the vaginal orifice with creation of a covering seal by cutting and appositioning the labia minora and/or the labia majora, with or without excision of the clitoris (**infibulation**)

Type 4: All other harmful procedures to the female genitalia for non-medical purposes, for example: pricking, piercing, incising, scraping and cauterization

Figure 1. WHO Classification of Female Genital Mutilation Types (adapted from(2, 3))

1.3 Impacts associated with FGM/C

FGM/C contravenes the human rights of women and girls(8) and reportedly has a profound impact on affected women and girls. However, it can form an important part of female cultural identity(9) and is perceived by many as an integral part of social conformity in line with community identity(10). FGM/C purportedly continues to be practiced due to ingrained traditional cultural belief systems of many communities globally(11). There are immediate and lifelong health, obstetric, sexual functioning, psychosocial, and economic impacts associated with FGM/C(9, 12-19). The risks of adverse outcomes appears to be greater the more extensive the FGM/C(17), with 9 in 10 type 3 FGM/C-survivors reporting complications(20). The consequences of type 3 FGM/C may lead to loss of life and reduced quality of life(12, 21). In addition to the well-established impact of FGM/C on women and girls, there is increasing evidence that highlights the adverse effects on men(22) suggesting that FGM/C can no longer be identified as an issue only affecting women(23). Men have conflicting views on the practice of FGM/C influenced by their social and cultural beliefs, however, many perceive themselves to be victims of the consequences(22). These consequences include psychological dissatisfaction and sexual frustration(24, 25).

1.4 Deinfibulation for type 3 FGM/C-survivors

Deinfibulation is a procedure to surgically release the narrowed vaginal introitus in women and girls with type 3 FGM/C(26). The WHO has reported(26) that deinfibulation is associated with improved health and well-being, as well as allowing sexual intercourse and childbirth. However, currently, there is only limited direct evidence to support this statement. For example, a recent systematic review could find no evidence that deinfibulation improved urologic complications(27). There is however stronger, albeit of very low quality observational evidence, to suggest that deinfibulation is associated with improved gynaecologic and obstetric outcomes(28). Deinfibulated women were at significantly less risk of having a caesarean section (odds ratio (OR) 0.19; 95% confidence interval (CI) 0.09, 0.39; 2 studies) and postpartum haemorrhage (OR 0.31, 95% CI 0.12, 0.83; 1 study) compared to type 3 FGM/C women without defibulation(28). Deinfibulated women were at similar risk to women without FGM/C of episiotomy (OR 0.79; 95% CI 0.61, 1.02; 2 studies), caesarean delivery (OR 0.60; 95% CI 0.33, 1.10; 1 study), vaginal lacerations (OR 0.80; 95% CI 0.39, 1.65; 1 study), postpartum haemorrhage (OR 2.52; 95% CI 0.49, 13.07; 1 study), blood loss at vaginal delivery (mL) (mean difference (MD) 9.50; 95% CI -15.47, 34.47; 1 study), length of second stage of labour (hours) (MD -0.18 hours; 95% CI -2.47, 2.10; 2 studies), length of hospital stay (days) (MD -0.30; 95% CI -0.69, 0.09; 1 study)(28).

1.5 Timing of deinfibulation for type 3 FGM/C-survivors

To date there has been slow progress in the development of evidence-based care to improve health outcomes for FGM/C-survivors, in particular, around the optimal timing of deinfibulation(26, 29, 30), with recommendations typically based on expert opinion rather than robust evidence(29). Deinfibulation can be undertaken outside of or during pregnancy(30). There is however considerable variation within and between clinical recommendations for when deinfibulation should take place(29). For example, Royal College of Obstetricians and Gynaecologists (RCOG) guidelines(31) recommend that deinfibulation should be offered prior to pregnancy and preferably before first sexual intercourse. These guidelines also state that deinfibulation can be performed antenatally, in the first stage of labour, at delivery, or perioperatively after a C-section. Royal College of Nursing (RCN) FGM guidance(32) does not provide a

clear indication on the optimal timing of deinfibulation with one statement indicating that deinfibulation is best performed when not pregnant and another that deinfibulation is best undertaken before or at least within the second trimester of pregnancy. WHO guidelines on the management of FGM/C(26) recommend either antepartum or intrapartum deinfibulation with a suggestion that timing should be based on wider contextual factors including: patient preference, access to health-care facilities, place of delivery and the HCPs skill level. In addition to a lack of consensus about when deinfibulation should be performed, there is also debate about whether timing affects outcomes with some individual studies suggesting that obstetric risks increase the later deinfibulation is undertaken(33, 34), although these findings were not substantiated in a recent systemic review of low quality observational evidence comparing childbirth outcomes between antepartum and intrapartum deinfibulation(30). This review(30) did however report that the limited data show a benefit for deinfibulation.

1.6 Deinfibulation experiences and timing preferences of women, men and HCPs

As highlighted by the WHO guidance(26), it important to consider the deinfibulation timing preferences of type 3 FGM/C-survivors, their partners and HCPs when making clinical decisions about intervention. Overall, there appears to be relatively little direct evidence around timing preferences for deinfibulation. The current evidence base explores more general experiences of deinfibulation for women, and broader experiences of FGM/C for men and HCPs(35). A recent qualitative evidence synthesis reported that immigrant women from high income countries may not be willing to undergo deinfibulation as they were concerned about their physical appearance and social acceptability following the procedure, as well as highlighting fears about the skills and experiences of HCPs providing deinfibulation care(35). A small qualitative study of Somali women's experiences of antenatal and intrapartum care in England, not included in the evidence synthesis, has highlighted that women consciously delayed deinfibulation until labour to avoid undergoing multiple operations(36). As far as the authors are aware there have been no qualitative studies that have directly explored men's preferences for the timing of deinfibulation and unlike studies of women's experience of deinfibulation(35), does not appear to be discussed in studies with a broader focus on men's experiences of FGM and their role in abandonment of the practice(22). Studies of HCPs views on the timing of deinfibulation are also scarce. Norwegian HCPs reported that they had unresolved questions about where, when and how to perform deinfibulation and where deinfibulation was required; they did not consider women's preferences (37). Uncertainty around how to undertake deinfibulation led to "improvisation" and advocacy of deinfibulation at various time points without a clear rationale or consensus in a study of Swedish HCPs(38).

2 Why is this research needed now?

FGM/C remains a significant global public health concern and is likely to become an increasingly important healthcare challenge in the UK owing to rising levels of immigration of women and girls from FGM/C-affected communities(6). The NHS will increasingly be required to provide culturally acceptable evidence-based care to growing numbers of FGM/C-survivors. In 2011, it was estimated that 137,000 women and girls were reported to be living with the consequences of FGM/C in England and Wales(7). Of the women and girls aged 15-49 with FGM/C 53,000 were born in countries where type 3, the most extensive type of FGM/C, is practiced almost universally. In addition, FGM/C-

survivors account for up to 1.5% of all women giving birth in England and Wales. These figures may be an underestimate of the true prevalence of FGM/C in the UK given the sensitive nature of disclosure, language barriers and the often limited engagement of FGM/C-survivors with healthcare services. This lack of engagement with FGM/C care services is likely to reflect a complex picture including the fact that there may be an absence of FGM/C service provision across the UK.

Type 3 FGM/C is associated with significant health, psychological, and economic consequences that impact girls, women and men(9). The WHO has suggested that deinfibulation is beneficial for the health and well-being of girls and women and reduces the risk of negative outcomes in childbirth(26). Currently however, there is no clear consensus on the optimal timing of deinfibulation for type 3 FGM/C-survivors (26, 29, 30). Recommendations for future FGM/C research suggest that "there is a urgent need for well-designed research to inform evidence-based guidelines, and to improve the healthcare of women and girls with FGM/C" (29)(pg.8). In addition, there is a specific need to focus on exploring preferences for timing of deinfibulation, involving a diverse range of FGM/C-survivors, their male partners, and HCPs, across multiple centres (29, 35). To date, there has only been one qualitative study which explicitly explored women's lived experiences of deinfibulation in the UK(39), and as far as the applicants' are aware, there have been no qualitative studies exploring the views of men and HCPs in the UK.

Our critical review of the current evidence base highlights that clear 'Silences' (see Figure 2 for information about the theoretical underpinning of the proposed research) exist around experiences of FGM/C and, in particular, deinfibulation and that there are potential substantial 'gains' from undertaking further research to inform NHS policy and practice. It therefore makes sense, as a starting point to inform NHS policy and best-practice, as well as adding to the limited qualitative evidence base, to undertake methodologically robust qualitative research with UK key stakeholders (type 3 FGM/C-survivors, their male partners, and HCPs) exploring their preferences for the timing of deinfibulation. The results of the proposed research may help to (a) inform the development of NHS services that are culturally acceptable and deliverable leading to improved outcomes for thousands of women and their families, (b) inform FGM/C guidelines, (c) inform the strategic and cost-effective planning of local NHS services now and for the future in both high and low prevalence settings, and (d) help other organisations (e.g. local authorities, third sector organisations) to develop plans to better support FGM/C-survivors and their families.

3 Theoretical Framework

This empirical qualitative research is informed by the *Sound of 'Silence'* ('Silences') conceptual framework(40). The 'Silences' framework is underpinned by broader theoretical approaches and is derived from anti-essentialist viewpoints which accept that reality (or 'truth') is neither objective, nor *fixe*, rather the social world is influenced by people in a particular society at a particular point in time(41). 'Silences' define areas of research and experiences that are little researched, understood or 'silenced'(42) and is specifically useful for researching sensitive issues and/or the healthcare needs and perspectives of marginalised populations(40). Within the context of the proposed study, although FGM/C is a contemporary issue that has increasingly become the subject of political and media interest it remains a sensitive issue that is prevalent amongst marginalised populations and one that is still under-researched.

'Silences' elucidates and underpins the research using a four-stage approach: (a) working in Silences, (b) hearing Silences, (c) voicing Silences, and (d) working with Silences (Figure 2). There is an additional fifth stage (e) planning for Silences, that is not incorporated into the core four-stage model, but will be used to help inform service delivery action planning and future recommendations for research, policy and practice.

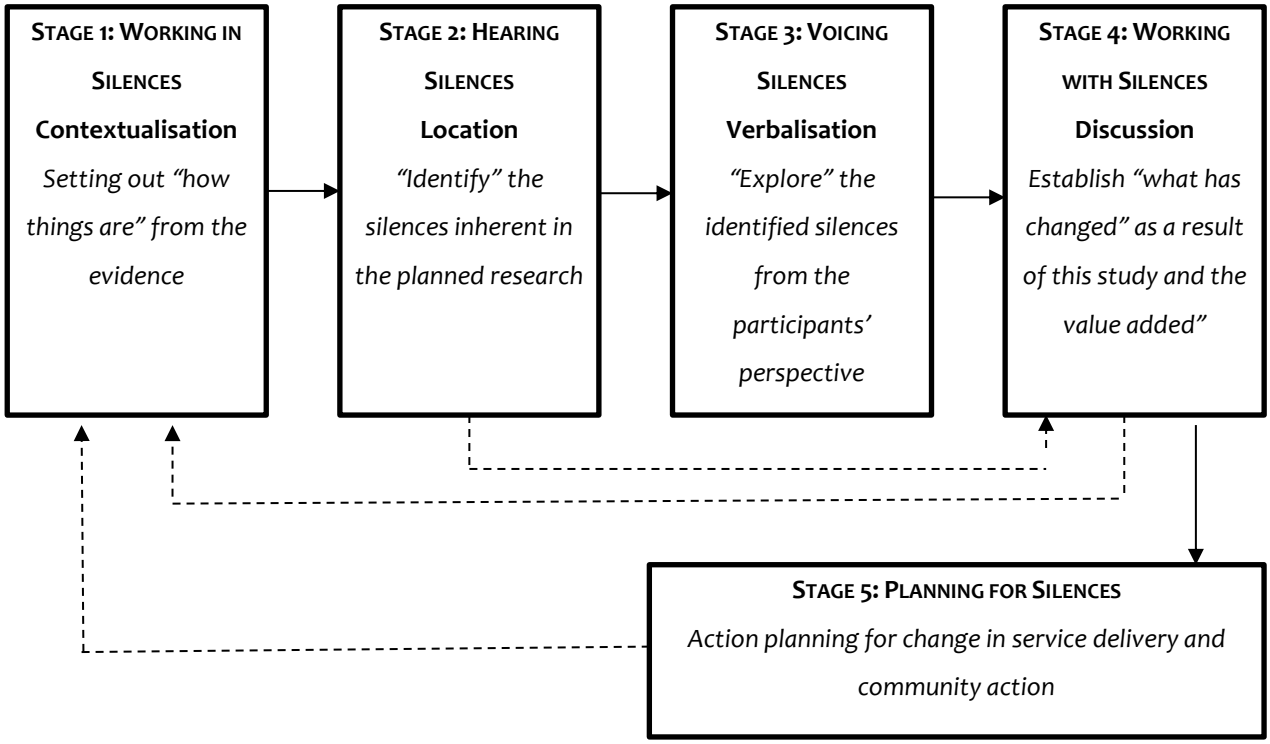


Figure 2. Sound of Silence (Silences) Conceptual Framework (adapted from(40))

4 Research Aims, Objectives and Outcomes

4.1 Overall Study Aim

To explore and understand FGM/C-survivors', their male partners' and HCPs' preferences for the timing of deinfibulation and their views on how NHS services can best be delivered to meet the needs of FGM/C-survivors and their families. This overarching aim will be addressed in two work packages (WP).

Work package 1

Aim

To qualitatively explore and understand the timing preferences for deinfibulation and how NHS FGM/C services could be improved for type 3 FGM/C-survivors (WP1a), their male partners (WP1b), and HCPs (WP1c).

Objectives

a. to explore knowledge, awareness and understanding of FGM/C and deinfibulation (WP1a,b,c)

b. to elicit views on preferences for the timing of deinfibulation and the rationale for these (WP1a,b,c)
c. to explore perspectives on the decision making process around deinfibulation (WP1a,b)
d. to explore knowledge, awareness, and experiences of FGM/C services and support (WP1,a,b,c)
e. to understand the enablers, motivators and barriers to FGM/C care seeking behaviours (Wp1,a,b)
f. to explore how HCPs describe, explain and reason about their care provision for FGM/C-survivors and their families (WP1c)
g. to understand how FGM/C care services could be improved to best meet the needs of FGM/C-survivors, their families and HCPs who support them in their local context (WP1,a,b,c)

Work package 2

Aim

To use established techniques to synthesise the qualitative research findings, inform best practice and policy recommendations around the timing of deinfibulation and FGM/C care provision, and identify future actions.

Objectives

a. to explore views and reflections on the trustworthiness of our interpretation of the data and the conclusions drawn (WP2a,b)
b. to establish if there is consensus about the optimal timing of deinfibulation (WP2a,b)
c. to identify the key recommendations to inform NHS FGM/C care provision (WP2a,b)
d. to explore the facilitators and barriers to implementation of changes to NHS FGM/C care provision (WP2b)
e. to explore views on the requirements for future FGM/C research (e.g. RCT) (WP2b)

4.2 Outcomes

The results of the proposed research may help to (a) inform the development of NHS services that are culturally acceptable and deliverable leading to improved outcomes for thousands of women and their families, (b) inform FGM/C guidelines, (c) inform the strategic and cost-effective planning of local NHS services now and for the future in both high and low prevalence settings, and (d) help other organisations (e.g. local authorities, third sector organisations) to develop plans to better support FGM/C-survivors and their families.

5 Study Design, Methods of Data Collection and Analysis

5.1 Study Design

The proposed qualitative research study, theoretically underpinned by the Sound of Silence conceptual framework(40), aims to explore and understand FGM/C-survivors', their male partners' and HCPs' preferences for the timing of deinfibulation and their views on how NHS services can best be delivered to meet the needs of FGM/C-survivors and their families. This aim will be addressed in two work packages (WP1 and 2). WP1 aims to qualitatively

explore and understand the timing preferences for deinfibulation and how NHS FGM/C services could be improved for type 3 FGM/C-survivors (WP1a), their male partners (WP1b), and HCPs (WP1c). WP2 aims to use established techniques to synthesise the qualitative research findings, inform best practice and policy recommendations around the timing of deinfibulation and FGM/C care provision, and identify future actions.

5.2 Data collection

Work package 1

Data collection and analysis are undertaken in Stage 3 'Voicing Silences' of the Silence conceptual framework and are informed by Stage 1 'Working in Silences' and Stage 2 'Hearing Silences'(40). In Stage 2, there are three aspects of the Silences which must be presented by the researcher in order for the reader to 'hear' them. These aspects relate to the possible silences that are inherent in researcher identity (who is undertaking the research and why), the research subject itself (why is the subject perceived as sensitive and/or under researched (informed by Stage 1)), and the nature of the research participants (identification of the Silences brought about by the marginalised discourses of those taking part). We will ensure that all three of these aspects are taking into account and reported transparently.

Semi-structured interviews have been identified as one of the most appropriate data collection method given that they can facilitate an in-depth exploration of participants' 'Silent' views(43) and are particularly useful in discussions of sensitive or traumatic experiences. In addition, based on further PPI representative feedback, discussion groups (focus groups) will also be used as an alternative data collection tool as representatives felt that women, in some communities such as Somali, may be more likely to participate in a group rather than individual discussion.

Interviews and discussion groups will be conducted by a trained qualitative researcher who will be independent of the participant's/participant's partner's clinical care team. Two researchers will be present in all discussion groups. Professional interpreters, who will receive specific FGM/C training by the research team (with support from the PPI advisory group) will be employed to provide real-time oral translation services during the interviews/discussion groups where there is a language barrier between the researcher and the participant. A debrief between the researcher and the interpreter will be held after each interview/discussion group to identify any translation issues, as appropriate. Where practicable we will try to use only a small pool of interpreters within each of the study locations. We will not support 'lay' or 'peer' interpretation by family and friends of the participants during the interviews/discussion groups given the social and cultural sensitives of the topic. Our PPI advisory group have highlighted that FGM/C is not openly discussed with their communities and therefore they would be very concerned about having lay/peer interpreters from within their own community involved in the study during formal data collection. Representatives said that this would potentially prevent participants from openly discussing their experiences. However, in order to facilitate recruitment of non-English speaking participants, lay interpreters may be used in telephone, text message and/or email discussions when arranging appointment times for interviews/discussion groups. Researchers will also keep a research journal throughout the data collection period to help to provide "reference points" in the journey to expose 'Silences'(40).

Participants will be given the choice as to whether they wish to take part in an interview or a discussion group. If they

choose to take part in an interview, they will be given a choice as to where the interview take place, for example, in their own home, in a private room where they were recruited (e.g. maternity unit), or via telephone (including Skype or other online communication tools). Discussion groups will be run in an appropriate pre-specified location, for example, in a Third Sector/Charity community venue, in a private room where they were recruited (e.g. maternity unit), or in a private room at the University of Birmingham (Birmingham location only). Aligned with Stage 2 'Hearing Silences'(40), individual discussion guides for WP1a-c will be informed by a critical reflection of the FGM/C evidence base. These 'Silences' will then be heard by and discussed within the research team and with the PPI advisory panel. Whilst semi-structured, interviews and discussion groups will be conducted in a participant-focused manner allowing experiences and views important to participants to emerge naturally(44). The composition of the participants in each discussion group will be carefully considered, taking into account the community from which they are from, their deinfibulation experience, and their wider demographic characteristics.

The discussions guides will be refined iteratively to ensure that all views are captured. Data collection and analysis will take place concurrently(43) and will continue until the research team judge that the data and sample have sufficient depth and breadth to address the research objectives(45). Either prior to or during the interview/discussion group participants will be asked to complete a short demographic questionnaire to facilitate maximum variation sampling and a description of the sample characteristics.

Work package 2

A community engagement event and a national stakeholder event will be run by FGM/C experts at Barnardo's (with support from the wider research team and the PPI advisory panel). Participants will be sent a plain English summary (drafted and discussed with the PPI advisory group) in advance of the workshops. At the start of each event, a tailored presentation giving an overview of the study will be delivered. Participants will then be split into smaller discussion groups which will be facilitated by a member of Barnardo's and supported by a member of the research team and/or PPI advisory group. Decisions on how the participants will be split will depend on who consents to participate. Discussion groups were identified as an appropriate data collection method given that they provide an opportunity for interaction and communication between participants in order to generate data and can provide a permissive and empowering environment where participants feel comfortable enough to share their views and question those of others(46-48). Discussion will focus on the participants' reflections of the trustworthiness of our interpretation of the data and the conclusions drawn; an exploration of "what has or can change as a result of this study" (aligned with Stage 4 'Working with Silences'(40)) in terms of NHS policy and practice, and identification of future research to address other identified 'unheard Silences'(40). Recommendations from each group will then be shared and discussed within the whole group to establish if a consensus on timing of deinfibulation can be reached and to identify the next steps following the completion of the proposed research.

5.3 Data analysis

Interviews, discussion groups and events (both the small and whole group discussions) will be digitally audio recorded and transcribed verbatim by an external specialist transcription company and subsequently checked for quality and

anonymised by the research team. Where resources allow, up to six transcripts (2 in Somali, 2 in Arabic, 2 in French) will have both the English and second language translated and transcribed. Early translation (i.e. prior to the start of data analysis) is recommended as it facilitates a more interactive process of data analysis between researchers and translators and helps to inform future data collection(49). Translation will focus on semantic and conceptual equivalence across the languages (English, Somali, Arabic and French) rather than direct word for word translation and a translation lexicon will be developed(50, 51). We will also seek validation of the translations by our bi-lingual PPI advisory group. Where practicable we will try to use only a small pool of translators.

Data analysis will be informed by the Framework Approach(52), which has been advocated for use in multidisciplinary health research(53). The Framework Approach provides a systematic and flexible model for managing and mapping qualitative data from multiple sources. The generation of a matrix will provide an intuitively structured overview of the data and facilitate exploration of patterns within and between data. Aligned with the analysis stages outlined by Gale *et al.*(53), but adapted to suit discussion group data, our inductive framework will be developed iteratively, using constant comparison, to facilitate systematic comparisons across cases to refine each theme. This is in line with the Silences conceptual framework which proposes that analysis should be phased and cyclical(40). Stage 3 'Voicing Silences' involves 4 phases of analysis: (a) researcher review (initial findings generated), (b) Silence dialogue (draft 1 of findings generated), (c) collective voices (draft 2 of findings generated), and (d) researcher reflection (reflection of phases 1-3 for final findings output)(40). Although not aligned with a particular epistemological, philosophical, or theoretical approach the Framework Approach is compatible with the anti-essentialist underpinning of the Silences Framework(40, 53).

6 Study Setting

Given the nature of the proposed research into 'Silent' and marginalised discourses(40) around FGM/C and the preferences for the timing of deinfibulation, we will involve multiple and multi-disciplinary collaborators (e.g. NHS Trusts and Third Sector Organisations (charities, advocacy and community groups)) across different regions, settings and services. FGM/C-survivors are resident in every local authority in England and Wales(7). The following regions have some of the highest prevalence rates of FGM/C-survivors: London (21.0 per 1,000 population), Birmingham (12.4), Manchester (16.2) and Bristol (14.8))(7). Birmingham is an ideal region to undertake this research given the high prevalence rate of FGM/C and the large numbers of migrants from FGM/C-affected countries, in particular, from countries who almost universally practice type 3, and so this will be the predominant area where the research is undertaken. In addition, we will attempt to recruit FGM/C-survivors and their male partners from London and Manchester. We have included London as practitioners report that London has a more transient FGM/C population, FGM/C-survivors are more likely to be type 3 and present in labour/at the point of delivery without having accessed care previously. For the work packages involving HCPs (WP1c and WP2b) we will attempt to recruit HCPs across the UK working in a variety of settings (e.g. primary and secondary care) in both high and low FGM/C prevalence areas.

7 Sample and Recruitment

7.1 Target population

Work packages 1a and 2a

Women who have experienced FGM/C and are currently resident in the UK. Please note that we have not specified the type of FGM/C based on feedback from our PPI representatives/specialist FGM/C clinicians who have highlighted that many women do not know which type of FGM/C they have experienced. We will therefore attempt to recruit as many type 3 women as is possible and will carefully document in the description of the sample the type of FGM/C reported by the participants (where possible).

Work package 1b

Male partners of women who have experienced FGM/C and are currently resident in the UK.

Work package 1c

Health care professionals including (but not limited to): general practitioners, practice nurses, midwives, obstetrics and gynaecology clinicians, genitourinary clinicians and sexual health specialists who currently or have recently (within five years) been involved in the delivery of care to FGM/C-survivors and their families in the UK.

Work package 2b

Key FGM/C stakeholders including (but not limited to): healthcare professionals identified above, policy makers, FGM-C specialist researchers/academics, health economists, commissioners, and representatives from Third Sector Organisations (e.g. Charities and Advocacy groups) who are currently or have recently (within five years) been involved in the delivery of care to FGM/C-survivors and their families in the UK.

7.2 Inclusion and exclusion criteria

Work packages 1a and 2a

Inclusion criteria: women aged 18 years and over; resident in the UK; speak fluent English, Somali, Arabic and/or French; willing and able to provide written, electronically completed or verbal (that is audio recorded) informed consent; have experienced FGM/C.

Exclusion criteria: psychological distress related to FGM/C which prevents them from consenting and/or participating.

Work package 1b

Inclusion criteria: males aged 18 years and over; resident in the UK; speak fluent English, Somali, Arabic and/or French; willing and able to provide written, electronically completed or verbal (that is audio recorded) informed consent; have a partner/wife or family member who has experienced FGM/C.

Exclusion criteria: partner/wife does not consent to their participation (if identified via a WP1a participant);

psychological distress related to FGM/C which prevents them from consenting and/or participating.

Work package 1c

Inclusion criteria: aged 18 years and over; speak fluent English; willing and able to provide written, electronically completed or verbal (that is audio recorded) informed consent; healthcare professionals (including but not limited to general practitioners, practice nurses, midwives, obstetrics and gynaecology clinicians, genitourinary clinicians and sexual health specialists) currently or recently involved (within the last 5 years) in delivery of care to FGM/C-survivors and their families in the UK.

Exclusion criteria: none.

Work package 2b

Inclusion criteria: aged 18 years and over; speak fluent English; willing and able to provide written, electronically completed or verbal (that is audio recorded) informed consent; key FGM/C stakeholder including (but not limited to) healthcare professionals (see list above), policy makers, FGM/C specialist researchers/academics, health economists, commissioners, representatives from third sector organisations (e.g. Charities and Advocacy groups) currently or recently involved (within the last 5 years) in delivery of care to FGM/C-survivors and their families in the UK.

Exclusion criteria: none.

7.3 Sampling

Serrant-Green, in her Silences conceptual framework(40) highlights the importance of hearing the personal experiences of marginalised discourses and that studies should include those with their own direct experiences (FGM/C-survivors). In addition, studies should include the perspectives of those belonging to the social-networks of the participants (male partners) and professionals (HCPs) to collate indirect evidence on viewpoints and roles that may impact participants' direct experiences of a particular issue.

Work package 1a

Four groups of pregnant and non-pregnant FGM/C-survivors will be purposively sampled(54) including those: (a) who have not had deinfibulation; (b) who have had deinfibulation for health and/or personal reasons, (c) who had deinfibulation antenatally, and (d) who had deinfibulation during labour/at the point of delivery. Within these 4 groups we will try to ensure we have a maximum variation or diversity of views by including women from a range of FGM/C-affected communities (e.g. Somali, Yemeni, Eritrean), locations, ages, and education levels(55). Women will be recruited via multiple pathways including: their HCP; advertising within FGM/C clinics, community settings, and on social media; culturally sensitive snowballing(56) from women approached to participate, and FGM/C community groups/third sector organisations. Multiple NHS trusts and Third sector Organisations (e.g. Charities and Advocacy groups) have agreed to support the study, including helping with recruitment and dissemination. In Birmingham these include: University Hospitals Birmingham NHS Foundation Trust, Birmingham Women's and Children's NHS Foundation Trust, Sandwell and West Birmingham Hospitals NHS Trust, Birmingham Against FGM, Birmingham and

Solihull Women's Aid; in London:, Chelsea and Westminster Hospital NHS Foundation Trust, The Hillingdon Hospitals NHS Foundations Trust, Imperial College Healthcare NHS Trust, London North West University Healthcare NHS Trust, and in Manchester: Manchester University NHS Foundation Trust, WarmHut UK. We will approach further Trusts and Third Sector Organisations as needed to ensure sufficient participant numbers.

Work package 1b

Men will be identified via participants from WP1a and via the support of local community groups and third sector organisations.

Work package 1c

HCPs will be purposively recruited(54) from (but not limited to) the following groups: GPs and practice nurses (up to 10 participants in total), midwives (up to 15 participants in total), obstetrics and gynaecology clinicians (up to 15 participants in total), genitourinary clinicians and sexual health specialists (up to 10 participants in total). HCPs across the UK will be identified via multiple pathways including via: FGM/C service listings (e.g. Barnardo's National FGM Centre(57), the FORWARD Foundation(58) and NHS Choices website lists(59)); contacting NHS Trusts with maternity services in low FGM/C prevalence areas directly; the applicants' own FGM/C networks; advertising the study via electronic communications (e.g. social media), professional bodies and membership societies, and snowballing from HCPs approached to participate. Recruitment of HCPs in low FGM/C prevalence areas will be facilitated by the Barnardo's FGM Centre who run a programme with six low prevalence local authorities (Essex, Norfolk, Suffolk, Southend, Hertfordshire and Thurrock) and so already have active links with HCPs who work in these areas.

Work package 2a

FGM/C-survivors who take part in WP1a will be invited to participate. If required, recruitment will be supplemented via the same pathways as identified in WP1a above.

Work package 2b

HCPs who are interviewed in WP1c will be invited to participate. Other key stakeholders (e.g. third sector organisations, academics, health economists, policy makers and commissioners) will be identified via the research teams' networks and collaborators and knowledge of FGM/C services acquired during the study.

7.4 Recruitment and Sample Identification

Advertising

There has been significant discussion with our specialist FGM/C clinicians and PPI representatives about "formal" advertising of the study. In general, it was felt that we should have a study advert but advertising needs to be discrete and strategic for work packages 1a (FGM/C-survivors) and 1b (male partners). This originates from the fact that FGM/C is simply not talked about openly, it's a highly sensitive and divisive topic. Representatives reported that "traditional" research study adverts were simply not appropriate and may in fact alienate the FGM/C-affected communities that we are trying to actively engage. Our PPI representatives and FGM/C specialist clinicians felt

recruitment would primarily need to come via trusted networks (e.g. a midwife or FGM/C support worker). However, they did support the use of discrete study information cards (including the FGM Sister Study logo and the research team's contact details only) and brief information sheets (a pared down version of the participant information leaflet). These could be offered to women on a case by case basis following the initial approach from a trusted advocate and they can choose which, if any study information, they wish to take away. Representatives also suggested that study information cards and brief information sheets could be left in discrete places (e.g. women's bathrooms) where a woman could pick them up without drawing attention. The study will also be advertised via social media platforms where survivors, men and HCPs will be able to self-identify.

Work package 1

With support from the Clinical Research Network (CRN), NHS Trusts and Third Sector Organisations opportunities for recruitment (e.g. where is this potential interaction with women who have experienced FGM/C) will be identified (e.g. specialist FGM/C services, antenatal and gynaecology clinics, community events). All participant identification sites will be trained by the research team (via a site initiation visit or equivalent) to approach potential FGM/C-survivors. Women will be approached, in the first instance, by a member of their usual care team (e.g. midwife) or by a trusted advocate (i.e. FGM/C support worker) in Third Sector Organisations. Recruiters will be asked to screen briefly for eligibility and to introduce the study. This may be done verbally or using a film clip (stand alone or accessed via the study website). All documents/films to support participant identification and recruitment will be available in multiple languages. Where possible, a member of the research team will be available to support recruitment, following the initial approach. If the woman responds positively, she will be asked to complete and sign a contact detail form giving her permission to be contacted by the research team. The research team will then contact the woman to arrange a mutually convenient time and location for the interview or to let her know the times and locations of discussion groups. At the end of the interview/discussion group women will be asked discretely if their partner may wish to participate in the FGM Sister Study, if she responds positively, then contact details of the research team will be left or the man recruited at that point if he is present. Men will also be approached via Third Sector Organisations in the same way as the women. For HCPs, study information will be disseminated to the target populations by practice managers, team leaders and professional bodies/membership societies. In addition, recruitment will be facilitated via social media platforms. Following this, interested potential participants will be asked to contact the research team using the provided contact details. Participants will then be followed up to ask screening questions, provide further study information, and to arrange an interview time and location of the participants' preference, via SMS/email and/or phone communication. They will be asked to disseminate the study information to any colleagues who may be eligible and interested in study participation.

Work package 2

Women and HCPs who participate in an interview/discussion group will be asked at the end if they would be willing to take part in the community engagement/stakeholder workshops. We will then contact them directly using the contact

details provided for the interview/discussion group closer to the date of the workshops and invite them to participate. Other stakeholders will be approached in the same way as the HCPs were for the interviews including via social media platforms.

7.5 Anticipated Sample Sizes

Work package 1 (total n up to 110)

We will seek to recruit (via a combination of interviews and/or discussion groups):

- up to 50 women who are FGM/C-survivors
- up to 10 male partners
- up to 50 healthcare professionals

Work package 2 (total n up to 60)

We will seek to recruit:

- 20-25 FGM/C-survivors for the community engagement event
- 30-35 stakeholders for the national stakeholder event

Numbers will remain flexible to ensure that we collect sufficiently rich data to answer the research questions and achieve core analytic saturation(45).

7.6 Consent

Subsequent to consent to contact (following the initial approach), the research team will liaise with participants via telephone, SMS and/or email, to answer any questions about the research, confirm eligibility, and arrange an appropriate opportunity for an interview or to inform them of the date/time/location of the discussion group or event. Eligible participants will be invited to take time to consider participation carefully. It will be made clear that involvement in the study is voluntary and that they are free to withdraw up to two weeks after the data collection event without giving a reason. They will also be reassured given the focus of the study that their participation will be kept in the strictest confidence (with the exception of disclosure of certain activities, for example, where individuals may be at risk of harm that requires further action). For participants whose first language is not English, participant information leaflets, background questionnaires, and consent forms will be available in alternative languages (including French, Arabic and Somali) to support the informed consent process. For those who decide to take part, participation instructions and appointment reminders will be sent via email/SMS or via phone ahead of each interview, discussion group or event. For those who wish to participate via a phone interview a participant information leaflet, background questionnaire, and consent form (in an appropriate language using specialist translation services) will be sent via post/email ahead of the scheduled interview with instructions on how to complete the forms and return them to the research team.

Written informed consent will be sought wherever possible. However, for example, in cases where the study related paperwork has not been received, not fully completed, or there are issues around literacy then we will seek alternative forms of informed consent including electronically completed (e.g. electronic completion of the form and scanning/photo of the completed consent form returned) or verbal (e.g. where the consent form will be read out in full and audio recorded at the start of the interview). Informed consent (including written, electronically completed and/or verbal (that is audio recorded)) will gain permission for agreement to participate, demographic data collection, audio recorded dialogue of discussion, and anonymised data sharing.. Trained specialist interpreters will be available (if required) to support the informed consent process and interpreters who have received FGM training will be available at the start of face to face and telephone data collection events. At the beginning of each audio recording, participants in the interview, discussion or event (small group discussions) will be asked to verbally (re-)confirm consent. Were formal verbal informed consent is being sought at the start of a phone interview, then the audio recorder will be switched on and the consent form will be read out (and translated as required by the interpreter), and the participant asked to consent to each statement. Should the participant not consent to any of the statements then the interview will be terminated at that point having explained to that participant that data collection cannot continue, as they did not consent to participate.

7.7 Inconvenience Allowances and Expenses

FGM/C-survivors and male partners will each receive a £20 shopping voucher for participation in an interview or discussion group. Discussion group participants will be provided with refreshments. If they travel to participate (e.g. to the University, Community Centre or hospital) then all reasonable travel expenses will be reimbursed. Healthcare professionals who travel to participate (e.g. to the University) will have any reasonable travel expenses reimbursed.

Participants in the community engagement event will be provided with refreshments, have their travel expenses covered, and will receive £50 in shopping vouchers to cover their time (following INVOLVE PPI guidance). Participants in the national stakeholder event will be provided with refreshments. For participants in the stakeholder event who do not have access to funds to support attendance, reasonable travel expenses will be reimbursed following receipt on an application for support to the chief investigator.

8 Ethical and Regulatory Considerations

8.1 Assessment and Management of Risk

Participants

FGM/C is a highly sensitive topic and one that may cause distress to participants during interviews/discussion groups. In view of this, a risk register will be maintained by the study management team in order to continually assess risk and implement actions to mitigate against, or reduce, risk. A review of risks will be completed on a monthly basis and any newly identified risks (actual or potential) will be added to the risk register for review and action planning.

It is clearly stated in the participant information leaflets, by the person introducing the potential participant to the study, as well as being reiterated by the researcher at the beginning of the interview/discussion group that participants are free to withdraw at any time up to two weeks after the data collection event without having to explain or justify their decision. All participants will self-select to take part and will be recruited via their own trusted networks. The welfare of the participants will always be placed ahead of the knowledge to be gained and emotionally distressing topics will be handled with sensitivity and sympathy and will follow the FGM Sister Study Distress Pathway (see Appendix 1). The interviewer/discussion group facilitator will also signpost the distressed participant towards services for additional support should this be appropriate. Information on support services is also provided in the participant information leaflet. We have sought PPI input to facilitate co-production and co-design of the study and all participant facing materials to ensure that they are sensitive and suitable for the FGM/C-affected communities where we will be undertaking the research.

FGM/C has been illegal in the UK since 1985. It is an offence under the FGM Act (2003) to (a) perform FGM/C in the UK or take a girl abroad to be subjected to FGM/C, (b) assist the carrying out of FGM/C in the UK or abroad, (c) assist from the UK a non-UK person to carry out FGM/C outside the UK on a UK national/permanent UK resident, and (d) for someone in the UK to aid, abet, counsel or procure FGM/C outside of UK. The Serious Crimes Act (2015) (a) provides anonymity for victims of FGM/C, (b) created a new offence of failure to protect a girl from FGM/C, (c) introduced FGM/C protection orders, and (d) introduced a mandatory reporting duty requiring regulated health and social care professionals and teachers to report known cases of FGM/C in under 18s to the police. Whilst the team in their capacity as researchers are not mandated to report known cases of FGM/C in under 18s; some members of the team are regulated healthcare professionals and the team feel that we have a duty of care to participants to follow the mandatory recording and reporting guidelines published by the Department of Health/NHS England. All members of the team will be trained on mandatory recording and reporting and where there are concerns following an interview/discussion group these will be discussed as a matter of urgency within the team and appropriate action taken as necessary.

Research Team

The research team may be exposed to sensitive and difficult discussions and/or vulnerable FGM/C-survivors (and their male partners) who live in challenging circumstances. Therefore, the risk register will include a section on mitigating and action planning for potential or actual risks to the research team. Debriefing sessions will be held within the research team as necessary to support the interviewer/discussion group facilitators. The Department of Health, as part of their Guidance on "Working Together to Safeguard Children" has proposed a Safeguarding Practice Reflection Framework that promotes effective professional supervision(60). This framework highlights that supervision "should support professionals to reflect critically on the impact of their decisions on the child and their family" and will we follow this model within this study. All members of the research team will have access to a more senior member of the team to talk through their concerns and decisions made in relation to the study. A further potential risk to the research team is that they may be undertaking interviews in the participants' homes, although the research team is experienced in using this data collection technique with FGM/C-survivors and their families. When contacting

participants to arrange an interview appointment the researcher will ask the participant about who else will be present during the interview, if there are dogs in the house, whether there is parking etc. If the researcher has concerns, these will be discussed within the research team. Where there are concerns and the participant is English speaking then an informed decision will be made about whether two members of the team attend the interview. Where there are concerns and the participant is non-English speaking then a translator will be present for the discussion and so the researcher will not be by themselves. When interviewing alone, the researcher will also follow the University of Birmingham Lone Worker Policy and will use a buddy system where another member of the research team is contacted upon arrival at the interview location and directly after the end of data collection. The other member of the research team will have access to the location and participant information.

8.2 Research Ethics Committee (REC) and other Regulatory Review/Reports

Regulatory Review and Compliance

The University of Birmingham is the nominated sponsor for this study. Via the Health Research Authority (HRA) approval system we will seek a favourable opinion from a research ethics committee (REC) and the required governance and legal compliance approvals. We will seek further local research governance, where required, from each of the Trusts and Third Sector Organisations involved in the study (e.g Barnardo's). Subsequent to favourable opinion and commencement of the study, any further substantial amendment[s] will not be implemented prior to endorsement from the Sponsor, responsible NHS REC and Trusts.

Amendments

Any amendment[s] to the study will be appropriately notified to the responsible NHS REC by the University of Birmingham, as the Sponsor. The NHS REC will provide a response regarding the amendment[s] within 35 days of receipt of the notice. It will be the Sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purpose of submission to the NHS REC. Substantial and non-substantial amendment[s], submitted via IRAS, will also be sent to the Research and Development department of each NHS Trust involved in the study to ascertain whether the amendment[s] may affect local NHS permissions. The amendment history will be tracked using version numbers [e.g. 1.0, 2.0] and dates to clearly identify the most recent protocol version.

8.3 Peer Review

The funding application, including the detailed study protocol, has undergone multiple rounds of high quality independent peer review in line with NIHR research funding guidelines. Following the submission of the expression of interest we received independent peer review from expert reviewers and the funding board. Following the submission of the full application, we received independent peer review from five expert reviewers, and further detailed feedback from the funding panel. The study team had the opportunity to respond to both sets of peer review and feedback from the board and requested changes were incorporated where appropriate in to the current study protocol.

8.4 Patient and Public Involvement

Aligned with the Silences framework(40) active and sustained PPI will be central to the successful delivery of the proposed study. Our co-applicant and PPI lead (HW), was born in an FGM-practising country and is an FGM/C-survivor and activist now living in the UK. She has continued to contribute to all aspects of the proposal and has helped to shape the PPI work that we have undertaken pre and post-award. HW acts as an important liaison between the research team (mainly academics and clinicians) and the PPI advisory group that we have established. The PPI advisory group (co-chaired by LJ and HW) currently includes four type 3 FGM/C-survivors all of whom have undergone deinfibulation. Three have had deinfibulation in the UK via a FGM/C clinic (one antenatally, one for health reasons, and one who was getting married). The fourth underwent "re-opening" on her wedding night in a different country by her partner. All four members have willingly agreed to support the study going forwards although they wish to remain anonymous in study documentation. Three have been involved since the start of the EOI application, with one joining the group at the start of the full application. We are currently in the process of trying to identify up to 2 other FGM/C-survivors to join the PPI advisory panel. Their continued participation is key to ensure that the proposed research is patient-focussed and centred around FGM/C-survivors needs. In addition, we have an FGM/C-survivor on the Study Steering Group.

The CI met face to face with all 4 members of the PPI advisory group with discussions focussing on: (a) views on the proposed study, (b) culturally appropriate language, (c) participation and recruitment of men, (d) use of interpreters, (e) use of videos/podcasts to support recruitment, (f) reviewing the plain language summary. Representatives reflected positively on the proposed study and highlighted the need for research to help to improve NHS FGM/C care. They stated that women do not understand what *'deinfibulation'* is and would prefer that we use either *'re-opening'* or *'reversal'* in all participant facing documents. They were encouraging of the use of videos/recorded materials involving native speakers from within the community to support recruitment alongside a "professional". They do think that it is important for us to talk to men, but felt that we should have multiple pathways to identify them including via the community and not just rely on participants from WP1a. The group were also keen to ensure that we can offer support to participants who may become distressed during interviews. Representatives reviewed and edited the plain language summary, helped to co-produce the patient facing materials, commented on the discussion guides, and have seen the final version of the protocol (V1.0).

The role and expectations of PPI advisory members will be formalised (e.g. by providing role descriptors, establishing terms of reference) at the start of the study. It is anticipated that we will run up to four half day PPI advisory group meetings across the 24 month study. These will be co-chaired (where possible) by LJ and HW with the support of ED. They will be held in mutually convenient locations and at a time that suits the majority of the group. Contributions from members and actions will be documented in the minutes of any study related meetings where PPI group members are present and on the NIHR HTA project monitoring system as and when required. In addition, contributions of the group will be acknowledged in any oral presentations/posters accepted in national/international conferences, study reports, and peer-reviewed publications. PPI representatives will receive appropriate payment, informed by INVOLVE guidance, for their participation.

8.5 Protocol Compliance

Accidental protocol deviations will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor. Serious protocol non-compliance will be reported without delay by research staff to the Chief Investigator and thence to the study Sponsor and onwards as appropriate. The Chief Investigator will ensure that the issue is investigated and appropriate actions taken. The responsible NHS REC will be notified as soon as possible of any serious breach of NHS REC approval conditions, any serious breach of security or confidentiality, or any other incident that could undermine public confidence in the research.

8.6 Data Protection and Patient Confidentiality

All study researchers, doctors, nurses, and midwives will uphold the core principles and comply with the requirements of the Data Protection Act 1998 and the EU General Data Protection Regulation 2016/679 in the collection, storage, processing, and disclosure of personal information. All study researchers, doctors, nurses, and midwives will also maintain up to date Good Clinical Practice [GCP] training.

The data protection measures of this study will adhere to the relevant policies and procedures of the University of Birmingham. All study data collected on paper will be held securely, in a locked room or locked cabinet that is accessible only to the research team and relevant regulatory authorities. All study data in electronic form will be held securely on encrypted machines protected by passwords. Audio files will be transcribed by a specialist external company subject to a Confidentiality Agreement to not disclose any information to third parties. Files will be transferred via a secure server with user identifiers and passwords. Transcripts will be marked with unique and anonymised identifiers. All data will be held securely in the custody of the Chief Investigator for a minimum of 10 years after publication of the main study results, in accordance with the University of Birmingham Research Data Management Policy.

8.7 Indemnity

The University of Birmingham, as the Sponsor, has in force a Public Liability Policy which provides cover for claims for "negligent harm." The activities of this study are included in the coverage. No provision has been made for indemnity in the event of a claim for non-negligent harm. Insurance and indemnity for NHS staff and participants recruited via NHS sites will be covered by standard NHS indemnity liability arrangements for clinical negligence claims in the NHS.

8.8 Access to the Final Study Dataset

Only the research team, the Sponsors relevant regulatory authorities, and the funder will have access to the final study dataset that will comprise demographic questionnaires, audio recordings and transcripts of interviews, discussion groups, community and stakeholder events. After publication of the main findings of the study, the research team will consider external requests to gain access to anonymised data, to be securely shared under the auspices of the chief investigator. The dataset will be preserved and available for this purpose for a minimum of 10 years following the end of the study. All requestors wishing to obtain study data will be asked to provide a brief

research proposal including the objectives and timelines of the candidate project, intellectual property rights, and expectations for publications and citations. These details will form the basis of a Data Sharing Agreement between the University of Birmingham and the requestor, to clearly establish the responsibilities of each party. It is expected that requestors will, as a minimum, acknowledge the original research team and NIHR funding, and will consider co-authorship of any subsequent publications, if appropriate. Permission for anonymised data to be shared for the purpose of future academic research will be sought from all participants via the informed consent form.

9 Dissemination Policy

9.1 Dissemination Plans

Study findings will be owned by the University of Birmingham. The PPI advisory group will contribute to the dissemination plan. The level of dissemination will be in keeping with that appropriate for a qualitative research study. Dissemination is likely to focus on: the findings of the qualitative research with FGM-survivors and their male partners; the qualitative research with HCPs working with FGM/C-survivors and their families (both papers will be reported against COREQ guidelines(61)); and the overarching policy and practice implications and recommendations of the research. We will submit up to three papers for publication in peer-reviewed academic journals and target relevant clinical/public and/or health audiences and those that target policy makers. Each paper will be openly accessible and we have included article processing charges in the costings. The number of qualitative papers will be determined by the conceptual richness of the data and whether one or two papers are required to best disseminate the results to appropriate audiences.

A monograph with an accessible lay summary (reviewed and approved by our PPI advisory group) will be prepared for the NIHR. An accessible, plain English research summary report (reviewed and approved by our PPI advisory group) will be disseminated to the study participants and the NHS Trust and Third Sector Organisations (e.g. Charities and Advocacy Groups) who have supported the study. Video clips/podcasts in multiple languages highlighting the key results and recommendations may be created and then disseminated via Trust and Third Sector Organisations' websites.

Presentations are likely to be delivered at national and international conferences (either by the research team or by our PPI lead and co-applicant (HW)) concerned with FGM/C, child and maternal health, safeguarding, research with marginalised communities, as well as, social and qualitative research methodologies. These are likely to include RCM, RCOG, WHO World Health Assembly and UNICEF annual conferences, as well as, the International Conference on Women.

We will work with the College of Medical and Dental Sciences' Head of Research and Knowledge Transfer Translational Research Manager and with the University's Public Engagement Committee to ensure our findings gain maximum impact. Public impact will be further enhanced through the applicants' local involvement with public, patient groups, clinicians and local authorities, national media engagement through personal links and the NIHR Press Office, the

University of Birmingham Press Office and the College of Medical and Dental Sciences' dedicated Marketing and Communications manager.

9.2 Anticipated Outcomes and Impact

This research is likely to contribute to future RCOG/RCN/RCM/NICE guidance on the management of and care provision for FGM/C-survivors and their families.

A monograph with an accessible lay summary (informed by our PPI advisory group) will be prepared for the NIHR.

An accessible, plain English report (reviewed and approved by our PPI advisory group) will be prepared for and circulated to FGM/C Third Sector Organisations.

Published paper(s): hearing, reflecting and reporting on the "Silences" relating to FGM/C and preferences for the timing of deinfibulation for FGM/C-survivors, their families and the HCPs who provide them with care.

Insights into conducting multi-disciplinary research across different locations and health settings into a sensitive area with marginalised communities.

Evidence on the optimal timing of deinfibulation and how NHS FGM/C care can be best provided for FGM/C-survivors and their families.

Research capacity building with further development around grant management and leadership for the PI (LJ) supporting the development of future research leaders.

Research capacity building with development of a more junior clinical researcher (ED) in the role of co-applicant and post-doctoral research fellow.

Provision of information and knowledge to FGM/C-survivors, their families and local communities to empower them to reflect on their FGM/C care seeking behaviours.

Giving our PPI lead and PPI advisory group an opportunity to directly inform the development and conduct of the research and giving them a voice with which they may take on future advocate roles within the wider FGM/C community.

Development of skills relating to public involvement in research.

9.3 Authorship Eligibility Guidelines

Individual contributions to the study will be reviewed with consideration for the authorship criteria of the International Committee of Medical Journal Editors [ICMJE], in order to determine authorship of any manuscript[s] submitted for publication.

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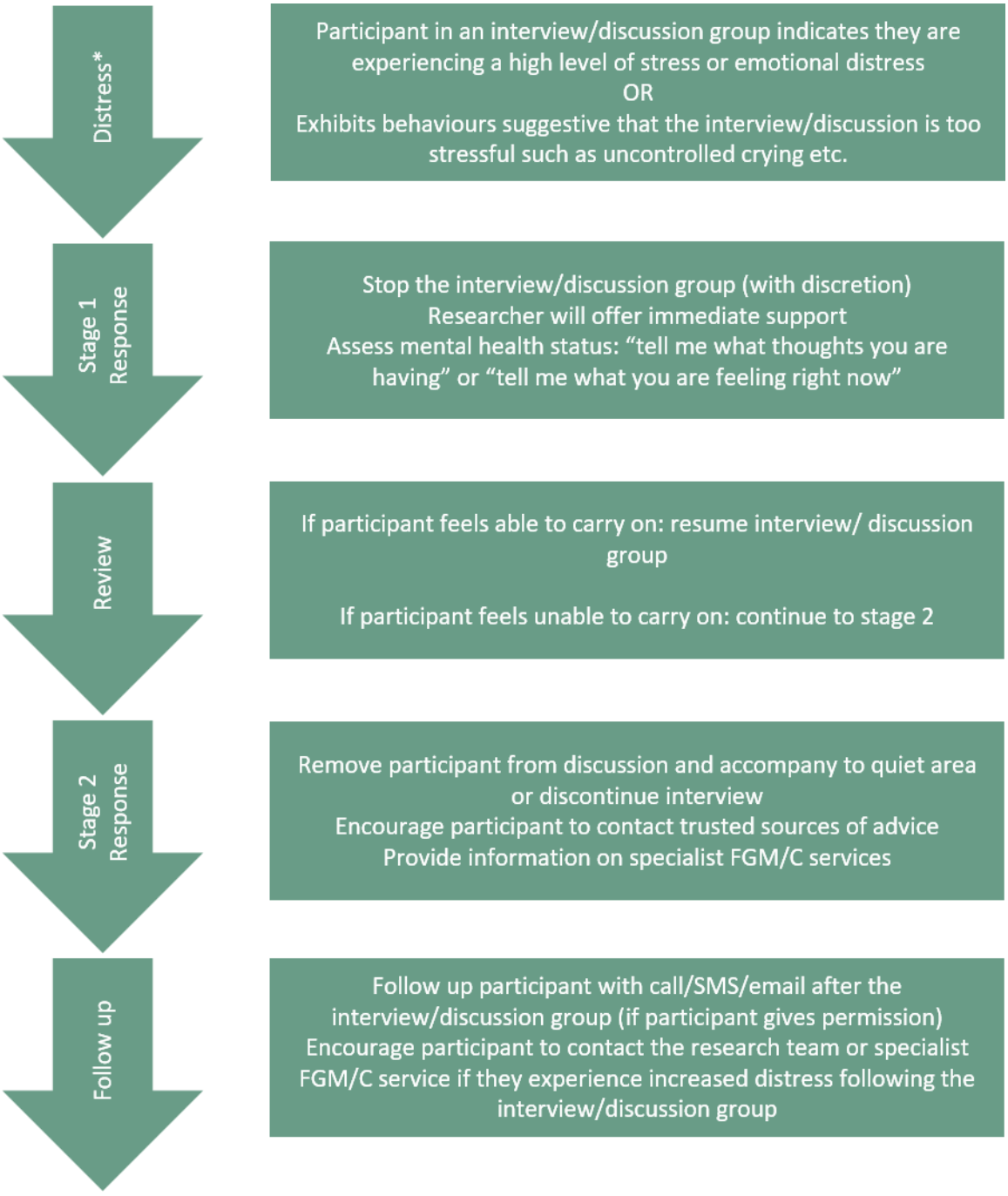
11 Appendices

11.1 Appendix 1 FGM Sister Study Distress Pathway



*Protocol for managing distress in the context of research on senstitive topics (Adapted from:(62))