

# FGM Sister Study: Exploring the views of female genital mutilation/cutting survivors, male partners and healthcare professionals on the timing of re-opening surgery

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| <b>Submission date</b><br>01/08/2018   | <b>Recruitment status</b><br>No longer recruiting            | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>17/08/2018 | <b>Overall study status</b><br>Completed                     | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results            |
| <b>Last Edited</b><br>23/03/2023       | <b>Condition category</b><br>Urological and Genital Diseases | <input type="checkbox"/> Individual participant data   |

## Plain English summary of protocol

### Background and study aims

Female genital mutilation, also known as female cutting (FGM/C), is a practice that involves changing, altering or removing part of a girl or woman's external genitalia without a medical or health reason. There are no health benefits, and some girls and women who undergo FGM/C may experience bleeding, pain, infections, and may have problems getting pregnant and giving birth. Some FGM/C-survivors may also experience mental health problems. Across the world, more than 200 million girls and women are affected by FGM/C, with 137,000 living with the consequences of FGM/C in England and Wales. The World Health Organisation has identified four different types (types 1, 2, 3 and 4) of FGM/C, with Type 3 (which involves creating a seal over the vaginal opening) being the most severe. Girls and women who undergo type 3 may need to have a small operation to re-open this seal (known as deinfibulation surgery). At the moment, we know little about what women, their partners, and healthcare professionals (e.g. doctors and midwives) think about when this operation should be done (e.g. before pregnancy or at what stage during pregnancy). We would also like to know more about how NHS services can best support and care for FGM/C-survivors and their families.

### Who can participate?

1. Adult women who are FGM/C survivors and can speak and/or write English, Somali, French or Arabic
2. Adult men who live in the UK and can speak and/or write English, Somali, French or Arabic, and have a wife, partner or family member who has experienced FGM/C.
3. Adult health care professionals who can speak fluent English and are currently (or have recently been) involved in the delivery of care to FGM/C survivors and their families in the UK.
4. Other key FGM/C stakeholders including (but not limited to) 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 been) involved in the care of FGM/C survivors and their families in the UK.

What does the study involve?

In order to understand when would be best for women to undergo re-opening surgery and how NHS FGM/C services could be improved we will carry out a programme of research that will include:

1. Discussions with up to 50 women with Type 3 FGM/C who have and have not been re-opened and up to 10 discussions with male partners to understand their views on when the operation should take place and how the NHS can best support their needs. FGM/C-survivors, from 3 different areas of England, will be identified via their healthcare professional, community organisations, advertising and word of mouth.
2. Discussions with up to 50 healthcare professionals (e.g. doctors, midwives, practice nurses) who care for FGM/C-survivors and their families across the UK to explore their views on when re-opening surgery should be undertaken and how FGM/C NHS services could be improved. Healthcare professionals will be identified via professional networks, FGM/C clinics, advertising and word of mouth.
3. Running two workshops (one with FGM/C-survivors and one with healthcare professionals) where we will discuss our findings from the programme of research, try to reach an overall decision about when re-opening surgery should take place, and make suggestions for how FGM/C-related care can be improved within the NHS.

We have asked a number of FGM/C survivors, who have and have not had re-opening surgery, to form a group to support the research team. The research team meet with the survivor group regularly to ensure that the research is appropriate and sensitive to the needs of FGM/C affected communities.

What are the possible benefits and risks of participating?

This research may not directly benefit the women and their families, but may help us to better understand the perspectives of FGM/C-survivors and their families which will hopefully improve FGM/C care in the future. We also hope that we will be able to provide healthcare professionals with guidance on when it is most appropriate to carry out re-opening surgery (deinfibulation) and what care is required at this time.

There are no physical risks to taking part. However, discussions may cause women and their partners and/or healthcare professionals to think and talk about things that may be upsetting. If this happens, we will ask the participant(s) if they wish to stop and have a short break, or if they want to stop completely. A list of specialist FGM/C organisations, who are experienced in supporting those affected by FGM/C, will be available to all participants.

Where is the study run from?

Institute of Applied Health Research, University of Birmingham (UK)

When is the study starting and how long is it expected to run for?

May 2018 to September 2020

Who is funding this study?

The National Institute of Health Research (UK)

Who is the main contact?

Dr Laura Jones

L.L.Jones@bham.ac.uk

## Contact information

Type(s)

Scientific

**Contact name**

Dr Laura Jones

**ORCID ID**

<https://orcid.org/0000-0002-4018-3855>

**Contact details**

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Egbaston  
Birmingham  
United Kingdom  
B15 2TT

## **Additional identifiers**

**Integrated Research Application System (IRAS)**

235256

**Protocol serial number**

IRAS ID: 235256, HTA: 16/78/04

## **Study information**

**Scientific 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)

**Acronym**

FGMSS

**Study objectives**

To explore and understand female genital mutilation/cutting (FGM/C) survivors', their male partners' and healthcare professionals' (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 aims to qualitatively explore and understand the timing preferences for deinfibulation and how NHS FGM/C services could be improved for:

- a) Type 3 FGM/C-survivors (WP1a)
- b) Male partners of type 3 FGM/C survivors (WP1b)
- c) Health care professionals (WP1c)

Work package 2 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 with type 3 FGM/C-survivors (WP2a) and key FGM/C stakeholders (WP2b).

**Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

1. Approved 16/08/2018, North West - Greater Manchester East Research Ethics Committee, 18/NW/0498
2. Approval of amendment 16/05/2019, North West – Greater Manchester East Research Ethics Committee (3rd floor, 4 Minshull Street, Manchester M1 3DZ), ref: 2.0 10th April 2019; IRAS project ID: 235256; REC Reference: 18/NW/0498

### **Study design**

Qualitative research study informed by the Sound of Silences conceptual framework

### **Primary study design**

Other

### **Study type(s)**

Other

### **Health condition(s) or problem(s) studied**

Female genital mutilation/cutting

### **Interventions**

#### **Work package 1**

Informed by the Silences Conceptual Framework, we will undertake qualitative semi-structured interviews and/or discussion groups with FGM/C-survivors (WP1a) and male partners of FGM/C-survivors (WP1b) living in three ethnically diverse cities in England (Birmingham, London or Manchester). Interviews and/or discussion groups with healthcare professionals (WP1c) working in high and low FGM/C prevalence settings and who provide care to FGM/C-survivors across the UK will also be undertaken.

Whilst semi-structured and informed by WP discussion guides, interviews/discussion groups will be conducted in a participant-focused manner allowing experiences and views important to participants to emerge naturally. The overall aim of the discussions is to understand timing preferences for deinfibulation and views on how NHS services can best be delivered to meet the needs of FGM/C-survivors and their families. Data collection will be supported by interpreters as necessary (Arabic, Somali and/or French), digitally audio recorded and subsequently anonymously translated and transcribed. Participants will be identified via pathways including NHS services, third sector organisations, and advertising and via word of mouth.

#### **Work package 2**

FGM/C experts from Barnardo's will run two face to face workshops. WP2a will involve a local community engagement event with FGM/C-survivors and WP2b a national stakeholder event with HCPs, third sector organisations, commissioners and policy makers. The workshops will focus on a reflection on the results of the study and provide an opportunity for consensus discussion about the timing of deinfibulation and make recommendations for NHS FGM/C care practice and policy. Participants will be sent a plain English summary of the study results ahead of the events. During each workshop a tailored presentation of the results will be delivered. Participants will be split into smaller facilitated discussion groups to discuss results and identify recommendations. Workshops will be digitally audio-recorded and transcribed. Participants will be identified via WP1, pathways including NHS services, third sector organisations, advertising, word of mouth, personal networks and collaborators.

## **Intervention Type**

Other

## **Primary outcome(s)**

An understanding of how 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. Data will be qualitative (with the exception of a non-validated demographic questionnaire that will allow us to describe the sample of participants) in nature including field notes, audio files and transcripts. Participants in work package 1 will take part in a one off interview or discussion group lasting between 60 and 90 minutes. Data will be collected over a 12-month period. Participants in work package 2 will take part in a one off discussion group lasting between 3 and 4 hours. Data will be collected over a six month period.

## **Key secondary outcome(s)**

N/A

## **Completion date**

30/09/2020

## **Eligibility**

### **Key inclusion criteria**

Work packages 1a and 2a:

1. Female
2. Aged 18 years or older
3. UK resident
4. Fluent in English, Somali, Arabic and/or French
5. Experienced female genital mutilation/cutting (FGM/C)
6. Willing and able to provide written informed consent.

Work package 1b:

1. Male
2. Aged 18 years or older
3. UK resident
4. Fluent in English, Somali, Arabic and/or French
5. Partner/wife or family member who has experienced FGM/C
6. Willing and able to provide written informed consent.

Work package 1c:

1. Aged 18 years or older
2. Fluent in English
3. Healthcare professional, including but not limited to:
  - 3.1. General practitioners
  - 3.2. Practice nurses
  - 3.3. Midwives
  - 3.4. Obstetrics and gynaecology clinicians
  - 3.5. Genitourinary clinicians
  - 3.6. Sexual health specialists
4. Currently or recently involved (within the last 5 years) in the delivery of care to FGM/C survivors and their families in the UK
5. Willing and able to provide written informed consent

Work package 2b:

1. Aged 18 years or older
2. Fluent in English
3. Key FGM/C stakeholder, including but not limited to:
  - 3.1. Healthcare professionals (see list for work package 1c)
  - 3.2. Policy makers
  - 3.3. FGM/C specialist researchers/academics
  - 3.4. Health economists
  - 3.5. Commissioners
  - 3.6. Representatives from third sector organisations (e.g. charities and advocacy groups)
4. Currently or recently involved (within the last 5 years) in the delivery of care to FGM/C survivors and their families in the UK
5. Willing and able to provide written informed consent

**Participant type(s)**

Mixed

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

141

**Key exclusion criteria**

Work packages 1a and 2a:

1. Psychological distress related to FGM/C, which prevents them from consenting and/or participating

Work package 1b:

1. Partner/wife does not consent to their participation (if identified via a WP1a participant)
2. Psychological distress related to FGM/C, which prevents them from consenting and/or participating

Work packages 1c and 2b have no exclusion criteria.

**Date of first enrolment**

01/09/2018

**Date of final enrolment**

23/01/2020

# Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

**University Hospitals Birmingham NHS Foundation Trust**

Birmingham Heartlands Hospital Princess of Wales

Women's Unit

Bordesley Green East

Birmingham

United Kingdom

B9 5SS

## Study participating centre

**Birmingham Women's and Children's NHS Foundation Trust**

Birmingham Women's Hospital

Mindelsohn Way

Birmingham

United Kingdom

B15 2TG

## Study participating centre

**Central Manchester University Hospital NHS Foundation Trust**

The Warrell Unit

St Mary's Hospital

Oxford Road

Manchester

United Kingdom

M13 9WL

## Study participating centre

**Chelsea and Westminster Hospital NHS Foundation Trust**

Gynaecology Out-Patients Department

Chelsea and Westminster Hospital

369 Fulham Road

London

United Kingdom

SW10 9NH

**Study participating centre****Sandwell and West Birmingham Hospitals NHS Trust**

Birmingham City Hospital

Dudley Road

Birmingham

United Kingdom

B18 7QH

**Study participating centre****The Hillingdon Hospitals NHS Foundation Trust**

Pield Heath Road

Uxbridge

United Kingdom

UB8 3NN

**Study participating centre****Imperial College Healthcare NHS Trust**

The Bays

South Wharf Road

St Mary's Hospital

London

United Kingdom

W2 1NY

**Study participating centre****London North West University Healthcare Trust**

Northwick Park Hospital

Watford Road

Harrow

United Kingdom

HA1 3UJ

**Sponsor information****Organisation**

University of Birmingham

**ROR**

<https://ror.org/03angcq70>



# Funder(s)

## Funder type

Government

## Funder Name

National Institute for Health Research

## Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

The protocol has been uploaded as an additional file (ISRCTN14710507\_Protocol V2.0\_10Apr2019) (added 28/10/2019)

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               |                               | 01/03/2023   | 23/03/2023 | Yes            | No              |
| <a href="#">Results article</a>               | primary outcome measure       | 26/12/2022   | 23/03/2023 | Yes            | No              |
| <a href="#">Protocol article</a>              | protocol                      | 17/10/2019   | 21/10/2019 | Yes            | No              |
| <a href="#">HRA research summary</a>          |                               |              | 28/06/2023 | No             | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |
| <a href="#">Protocol file</a>                 | version V2.0                  | 10/04/2019   | 28/10/2019 | No             | No              |
| <a href="#">Study website</a>                 | Study website                 | 11/11/2025   | 11/11/2025 | No             | Yes             |