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

Submission date
01/08/2018

Recruitment status
No longer recruiting

Registration date
17/08/2018

Overall study status
Completed

Last Edited
23/03/2023

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 menwho 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 toSeptemeber 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

Study website
http://www.birmingham.ac.uk/fgmsisterstudy

Contact information

Type(s)
Scientific

Contact name
Dr Laura Jones

ORCID ID
http://orcid.org/0000-0002-4018-3855

Contact details
Murray Learning Centre, Institute of Applied Health Research, University of Birmingham, Egbaston
Birmingham
United Kingdom
B15 2TT

Additional identifiers

EudraCT/CTIS number

IRAS number
235256

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a copy of the different participant information leaflets used in this study

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, work of mouth, personal networks and collaborators.

Intervention Type
Other

Primary outcome measure
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.

Secondary outcome measures
N/A

Overall study start date
01/05/2018

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

For work package 1, we will seek to recruit up to 50 women who are FGM/C-survivors (WP1a), up to 10 male partners (WP1b) and up to 50 HCPs (WP1c). For work pacakage 2, we will seek to recruit 20-25 FGM/C-survivors for the community engagement event (WP2a) and 30-35 stakeholders for the national stakeholder event (WP2b). Numbers will remain flexible to ensure that we collect sufficiently rich data to answer the research questions and achieve core analytic saturation.

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
England

United Kingdom

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

Sponsor details
Research Support Group
Aston Webb Building
University of Birmingham
Edgbaston, Birmingham
England
United Kingdom
B15 2TT

Sponsor type
University/education

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

Publication and dissemination plan
We will submit up to three papers (in addition to the protocol paper that will be submitted for review 01/09/2018) 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. 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.

Intention to publish date
01/10/2021

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?
Protocol article	protocol	17/10/2019	21/10/2019	Yes	No
Protocol file	version V2.0	10/04/2019	28/10/2019	No	No
Results article		01/03/2023	23/03/2023	Yes	No
Results article	primary outcome measure	26/12/2022	23/03/2023	Yes	No
HRA research summary			28/06/2023	No	No