

PARTICIPANT INFORMATION LEAFLET FGM/C-SURVIVORS



Female Genital Mutilation:

A qualitative study exploring the views of survivors, male partners and healthcare professionals on the timing of re-opening (deinfibulation) surgery

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🌐 www.birmingham.ac.uk/fgmsisterstudy

What will happen to the results of the study?

When the results of the study are known we will run an event to discuss them with the community. You may be invited to attend this event. We will also share the findings via our website (www.birmingham.ac.uk/fgmsisterstudy) and will publish the overall findings of the study in health journal(s), for consideration by the National Institute for Health and Clinical Excellence (NICE). Please note that you will not be identifiable in any study related report.

Who has organised and reviewed the research?

This study has been funded by the National Institute for Health Research (NIHR) (HTA: 16/78/04). It is organised, managed and coordinated by the University of Birmingham, and data will be collected and stored by this institution. The study is sponsored by the University of Birmingham.

The FGM Sister Study has been reviewed by the North West Greater Manchester East Research Ethics Committee. Additionally, the study will be supervised on a regular basis by a Study Management Group and a Study Steering Group.

The people caring for you (e.g. the doctors, midwives, or FGM support workers) will not receive any payments or other benefits for recruiting women into the study. At the end of the interview/discussion group you will be given a £20 shopping voucher as a thank you for your time. If you have travelled to the interview/discussion group then we will cover your travel expenses.

What if there is a problem?

If you are not satisfied with any aspect of the way in which you have been approached or treated during the course of this study, then please first speak to the researchers (our contact details are on the front cover of this information sheet).

If you wish to complain formally and were approached to take part in the study via a hospital, then the normal National Health Service complaints mechanisms will be available to you: please ask to speak to the Patients Advisory and Liaison Service (PALS) Manager for the Hospital.

If you wish to complain formally and were approached to take part in the study anywhere other than in a hospital then you can contact the University of Birmingham Sponsor Representative: Dr Sean Jennings; University of Birmingham, Research Support Group, Room 119 Aston Webb Building, Edgbaston, Birmingham, B15 2TT ☎ 0121 415 8011 ✉ researchgovernance@contacts.bham.ac.uk

Where can I get further support?

Taking part in this study may bring back memories for you that you may find difficult. Below is a list of specialist organisations that can help if you feel that you need additional support. Staff at the specialist clinics have extensive experience in dealing with FGM/C. They are not there to judge you and are there to help.

Birmingham and Solihull Women's Aid	Ryland House, 44-48 Bristol Street, Birmingham B5 7AA bswaid.org	0808 800 0028 info@bswaid.org
Birmingham Heartlands Hospital	Birmingham Heartlands Hospital Princess of Wales, Women's Unit, Bordesley Green East, Birmingham B9 5SS	07817 534274 or 0121 424 3909
Warm Hut UK	Office G17 Technology House, 2 Lissadel Street Salford M6 6AP warmhut.org	0161 278 2758 info@warmhut.org.uk
St Mary's Hospital Manchester	The Warrell Unit St Mary's Hospital Manchester	0161 276 6570
Chelsea and Westminster FGM Service	Chelsea and Westminster Hospital Gynaecology out-patients department, 369 Fulham Road London, SW10 9NH www.chelwest.nhs.uk/services/womens-health-services/gynaecology-services/fgm-service	07812 378 363 caw-tr. fgmwestlondon@nhs.net
Forward UK	Suite 4.7 Chandelier Building, 8 Scrubs Lane London NW10 6RB forwarduk.org.uk/key-issues/fgm	0208 960 4000 support@forwarduk.org.uk
Barnardo's National FGM Centre	www.nationalfgmcentre.org info@nationalfgmcentre.org.uk	0208 498 7137

Thank you for taking time to read this information sheet and for considering taking part in the FGM Sister Study.



Developing excellence in response to FGM and other harmful practices

University Hospitals Birmingham NHS Foundation Trust



UNIVERSITY OF BIRMINGHAM | UNIVERSITY OF APPLIED HEALTH RESEARCH

National Institute for Health Research

FGM Sister Study - Patient Information Leaflet (FGM/C-Survivors) IRAS ID: 235256 v1.1, 30th July 2018

Key Study Summary

Why have I been invited to take part?

You have been invited because you are a woman living in the UK who has experienced female genital mutilation, also known as female genital cutting (we will use the abbreviation FGM/C from now on in this information leaflet).

What is the purpose of the study?

The aim of this study is to explore and understand FGM/C-survivors', their male partners' and healthcare professionals' preferences for the timing of re-opening surgery (also known as deinfibulation which is a small operation to re-open the seal created over a women's vagina in type 3 FGM/C) and their views on how NHS services can best be delivered to meet the needs of FGM/C-survivors and their families.

Do I have to take part?

Taking part is voluntary. If you decide to take part, you will be asked to sign a consent form but you will be free to withdraw up to two weeks after the interview/discussion group. If you do not wish to take part, you will not have to give a reason and your decision will not affect the care you will receive.

What are the benefits of taking part?

This research may not directly benefit you, but what you tell us may help us to better understand the perspectives of FGM/C-survivors and their families. We hope this will 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.

What are the risks of taking part?

There are no physical risks to taking part in this study. However, interview/discussion group may cause you to think and talk about things that are upsetting. If this happens, we will ask you if you want to stop and have a short break, or if you want to stop completely. At the end of this leaflet you can find a list of specialist FGM/C organisations who can help you if you feel that you need more support.

What is FGM/C?

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. 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.

What is re-opening (deinfibulation) surgery?

Girls and women who have experienced type 3 FGM/C may need to have a small operation to re-open their vaginal seal, known as re-opening (deinfibulation) surgery.

What will I have to do if I take part?

You can take part in two ways; firstly, you can choose if you would like to take part in a one to one interview or in a discussion group with a small number of other women who have also experienced FGM/C. Interviews will take around 60 minutes and discussion groups around 90 minutes. Interviews can be take place in a place where you are most comfortable, for example, at your home, in a private room in the place where you heard about this research or by telephone. Discussion groups will take place in safe location such as in the place where you heard about the study. If English isn't your first language then we can arrange for an independent and confidential interpreter to help translate. These discussions will be audio recorded to allow (1) the researcher(s) to pay full attention to what you are saying and (2) the research team to do further analysis at a later date. Secondly, if you agree to take part in an interview or discussion group, you may be given the opportunity to take part in a community meeting after the results of the study have been analysed.

What happens next?

You can talk to the person that gave you this information sheet for more information and they will ask you to complete a short questionnaire with your details. With your permission they will then pass these details on to the research team who will contact you discretely. Or if you would like to find out more, you can contact the research team directly using the details on the front of this information leaflet and we will get back to you.

What will happen to any information that I give?

The audio-recording of the interview/discussion group will be used to produce a typed record of the discussion, known as a transcript. This transcription will be done by a specialist transcription company who will sign an agreement to keep your data confidential and stored securely. The transcript will be anonymised, that is all identifying details such as names and locations will be changed to preserve confidentiality. If the interview/discussion group is conducted in a language other than English, the transcript will also be translated by a specialist translation service. We will analyse the anonymised transcripts as part of our research.

The University of Birmingham will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the University of Birmingham and regulatory organisations may look at your research records to check the accuracy of the research study. The NHS organisations and third sector organisations who may approach you about taking part in the study, with your permission, will pass your contact details to the University of Birmingham. The only people in the University of Birmingham who will have access to information that identifies you will be people who need to contact you, for example, to invite you to participate in the study or to audit the data collection process.

The University of Birmingham is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Birmingham will keep identifiable information about you until the main results of the study have been published, after this time, identifiable information will be safely destroyed. Anonymised data will be stored securely at the University of Birmingham for at least ten years after the end of the study. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information by contacting Dr Laura Jones (✉ L.L.Jones@bham.ac.uk; ☎ 0121 414 3024).

Will my taking part be kept confidential?

Yes. All information which is collected about you during the course of the research will be kept strictly confidential. However, if anything is raised during the interview/discussion group that indicates that either you or someone else is at risk of harm, then these concerns may need to be taken further. If there is an indication that you or someone else is at risk of significant harm then it is the duty of the researcher to share this information with the Police and local safeguarding teams. Equally, if FGM/C has occurred in the UK, it is the duty of the researcher to inform your local safeguarding team and the police.

Can I decide not to carry on with the study?

If you decide to take part in the study but then change your mind, you will be free to withdraw for up to two weeks after the interview/discussion group without giving a reason (although we will appreciate it if you tell us why you change your mind). Your care will not be affected in any way.

How will my GP know I am participating?

No, we will not inform your GP that you are taking part in this study.