

# Effects of reconstructive surgery on women who are circumcised: a longitudinal study

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The primary aim of this study is to gain more insight on the impact of reconstructive surgery on circumcised women. This study may also be used for theorizing about plastic surgery on women who are circumcised.

<b>Ethical review</b>	Not approved
<b>Status</b>	Will not start
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON34291

### Source

ToetsingOnline

### Brief title

The effects of reconstructive surgery

### Condition

- Other condition

### Synonym

correction of female genital mutilation

### Health condition

plastisch chirurgische ingrepen bij vrouwen die besneden zijn

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Pharos: kennis en adviescentrum migranten, vluchtelingen en gezondheid

**Source(s) of monetary or material Support:** In eerste instantie uit eigen middelen Pharos. Mochten er meerdere patiënten komen;wordt dan subsidie aangevraagd bij fondsen

## Intervention

**Keyword:** - female genital mutilation/cutting, - female genital reconstruction, - genital reconstruction

## Outcome measures

### Primary outcome

The difference between scores on questionnaires during different measuring moments.

### Secondary outcome

not applicable

## Study description

### Background summary

Female genital mutilation (FGM) comprises all procedures that involve partial or total removal of the external female genitalia, or other injury to the female genital organs for non-medical reasons. The mildest form of female genital mutilation is an injection/incision in the foreskin of the clitoris and the most severe form is infibulation (see study protocol p.4).

Due to migration, people originating from countries where FGM is practiced, live in the Netherlands.

FGM poses serious physical and mental health risks for women and young girls. A study in 2009 shows that FGM may have caused various psychological problems like depression, anxiety, PTSD and social problems such as anger, shame, guilt, loneliness and exclusion. The results of that study also show that FGM can have a significant impact on the relationship with the partner especially when it comes to sexuality (Vloeberghs et al. 2010).

Experience abroad regarding surgical procedures on women who are circumcised show that by surgical procedures where the clitoris is recreated, 72-75 % of these women were back to normal sexuality after 18 months. Recently the OLVG

hospital in the Netherlands offers an opportunity for reconstructive surgery for women who are circumcised. Depending on what has been cut during circumcision, the clitoris and/or labia recreated.

The purpose of this study is to examine the effect of reconstructive surgery on well-being (both physical and mental) and sexual functioning of women who are circumcised.

We expect that by reconstructive surgery the quality of life of patients will improve and in the long run they will have a higher self-esteem. We also expect that these patients will function better as it comes to sexuality on the long-term.

## **Study objective**

The primary aim of this study is to gain more insight on the impact of reconstructive surgery on circumcised women. This study may also be used for theorizing about plastic surgery on women who are circumcised.

## **Study design**

This is a longitudinal study in which patients will be approached at three different times to fill in the questionnaires: before surgery (baseline) and 3 and 12 months after surgery. The mean scores on the questionnaires at different measuring moments will be compared with each other. This study is exploratory because the effect of reconstructive surgery on women who are circumcised has not yet been studied.

## **Study burden and risks**

The patient fills in questionnaires at three measuring moments:

- RAND-36: 36 questions
- Female Sexual Function Index (FSFI): 19 questions
- Bekkenbodemp (Pelvic Floor): 47 questions
- Rosenberg's Self-esteem Scale: 10 questions
- LAS: 26 questions
- General questions: 6 open questions

## **Contacts**

### **Public**

Pharos: kennis en adviescentrum migranten, vluchtelingen en gezondheid

Herenstraat 35  
3507 LH

Nederland

## **Scientific**

Pharos: kennis en adviescentrum migranten, vluchtelingen en gezondheid

Herenstraat 35

3507 LH

Nederland

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

women with all forms of circumcision involving partial or total removal of the clitoris and/or small and/or large labia.

### **Exclusion criteria**

- women with congenital genital anomaly or other acquired genital abnormalities
- underage women (under 18)
- women who suffer from Post Traumatic Stress Disorder
- women who want to become pregnant

## **Study design**

### **Design**

**Study type:** Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

## Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	3
Type:	Anticipated

## Ethics review

Not approved	
Date:	14-02-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL33876.100.10