

Effect of reconstructive surgery on circumcised women well-being: a follow-up 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 (type I, 2 & 3). This study may also be used for theorizing about plastic surgery on women who are circumcised.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Therapeutic and nontherapeutic effects (excl toxicity)
Study type	Observational non invasive

Summary

ID

NL-OMON35828

Source

ToetsingOnline

Brief title

Reconstruction FGM

Condition

- Therapeutic and nontherapeutic effects (excl toxicity)
- Vulvovaginal disorders (excl infections and inflammations)
- Obstetric and gynaecological therapeutic procedures

Synonym

n.v.t

Research involving

Human

Sponsors and support

Primary sponsor: Pharos, Kennis- en Adviescentrum Vluchtelingen, Migranten en

Intervention

Keyword: Effect on well-being, Female Genital Mutilation/Cutting, Follow-up study (1 year), Reconstructive surgery

Outcome measures

Primary outcome

The difference between scores on the questionnaires during different measuring moments. The scores will be related and compared, on an individual level, with the outcome of the three interviews that take place with the help of a topic list.

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 after the reconstructive surgery the quality of life of the women will improve and that they, in the long run, may have a higher self-esteem. We also expect that these patients will feel better on the long-term when having sexual relations.

Study objective

The primary aim of this study is to gain more insight on the impact of reconstructive surgery on circumcised women (type I, 2 & 3). This study may also be used for theorizing about plastic surgery on women who are circumcised.

Study design

It concerns a follow up study in which respondents will be approached at three different times to fill in the questionnaires and have an interview: - i.e. before surgery (baseline) and 3 and 12 months after surgery. The mean scores on the questionnaires at different moments (T1 to T3) will be compared with each other. While the outcome of three interviews will be compared with the quantitative data on an individual level in order to reach saturation concerning our research objective.

This mixed method study is exploratory since the effect of reconstructive surgery on the quality of life (QoL) of women who are circumcised have not yet been studied. Hence we also do not have a control group included in the research.

Study burden and risks

not applicable

Contacts

Public

Selecteer

P.O. Box 13318
3507 LH Utrecht
NL

Scientific

Selecteer

P.O. Box 13318
3507 LH Utrecht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Migrant women in the Netherlands being genitally mutilated with a type 1, 2 or 3 circumcision who want to have this reconstructive surgery done in order to feel better.

Exclusion criteria

Genitally mutilated immigrant women in the Netherlands with a congenital genital anomaly or an acquired genital abnormality. Or if they suffer from severe mental health problems due to their mutilation and/or because of other reasons (e.g. conflict and war related psychopathology).

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:	10
Type:	Anticipated

Ethics review

Approved WMO	
Date:	19-09-2011
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	NL37339.100.11