

The effect of the exposure to a photo series of unaltered vulva's on the genital self image of women who are considering a labial reduction

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1. What is the effect of a photo series of unaltered vulvas on genital self image in women who consider a labial reduction.2. Does the diagnosis BDD; the reason to consider a labial reduction (aesthetic or functional); sexual functioning; sexual...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44676

Source

ToetsingOnline

Brief title

LR-study

Condition

- Other condition

Synonym

negative body image, Negative genital self image

Health condition

Stoornis in de lichaamsbeleving

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Indien er kosten zijn worden ze betaald uit inverdient geld door de afdeling zelf. Uitvoer onderzoek is door personeel in loondienst.

Intervention

Keyword: -Genital self-image, -Labial reduction, -Photo series of unaltered vulvas

Outcome measures

Primary outcome

Genital self-image measured using the Female Genital Self Image Scale.

Secondary outcome

- General preoccupation with an imagined bodily abnormality (BDD) as measured by the Cosmetic Procedure Screening (COPS)
- Preoccupation with an imagined abnormality of the labia, measured by the Cosmetic Procedures Screening for women seeking Labiaplasty (COPS-L)
- Motives for labial reduction (MvS)
- Sexual functioning, measured by the Female Sexual Function Index (FSFI)
- Sexual distress, Female Sexual Distress Scale-Revised (FSDS-R)
- Psychoneuroticisme measured by the Self-Assessment Questionnaire (ZBV)
- Susceptibility to arguments to refrain from a labial reduction (VAL)
- Decision labial reduction
- Labia size

Study description

Background summary

Increasingly, women are considering to undergo a labial reduction. Little is known about possible negative consequences of labial reductions. We are therefore studying the effect of a psychological intervention to have women abstain from requesting a labial reduction. Earlier studies suggest that healthy female subjects have a more positive genital self-image after having been exposed to a photo series of unaltered vulva's. In the present study we investigate whether a clinical population (women who are considering to undergo a labial reduction) also report a more positive genital self-image after being exposed to a photo series of unaltered vulva's (Experimental condition) relative to being exposed to a photo series of neutral objects (Control condition).

Study objective

1. What is the effect of a photo series of unaltered vulvas on genital self image in women who consider a labial reduction.
2. Does the diagnosis BDD; the reason to consider a labial reduction (aesthetic or functional); sexual functioning; sexual discomfort; the trait neuroticism have impact on the effect of the photo series of unchanged vulvas on genital self image in this group.
3. Are women in the experimental condition, in the impression of the attending gynecologist, more susceptible to arguments to refrain from the labial reduction compared with the women in the control Group?
4. What is the effect of a photo series of unaltered vulvas on the decision women make to undergo a labial reduction.
5. Is labia minora size associated with (1) genital self-image; (2) efficacy of the photo series of unaltered vulva's on genital self-image; (3) motives for undergoing a labial reduction.

Study design

It concerns a 2 (Condition; experimental versus control) x 2 (Time: before-versus after the intervention period) experimental study with random assignment to the experimental or control condition. With Condition as between-subjects factor and Time as within-subjects factor and genital self image as dependent variable.

Intervention

The photo series *Petals* by Nick Karras, which consists of different pictures

of unaltered vulvas.

Study burden and risks

Subjects will come for the study visit immediately prior to their outpatient visit to the gynecologist. The visit takes 1 hour. There are no risks associated with the intervention and there is no indication that seeing the photo series of unaltered vulvas will be experienced as unpleasant.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Women who consider labial reduction

Exclusion criteria

No understanding of the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	20-01-2014
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO	
Date:	18-12-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	21-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	14-02-2014

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-01-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL42385.018.13