# Quantitative assessment of the clitoral sexual arousal response in pre and postmenopausal women using magnetic resonance imaging

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Primary Objective: The primary objective is to study clitoral volume changes during sexual arousal in premenopausal women compared to postmenopausal women.Secondary Objective(s) are: To study whether there is an association between feelings of...

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| **Ethical review** | Approved WMO |
| **Status** | Completed |
| **Health condition type** | Sexual function and fertility disorders |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON53425

**Source**
ToetsingOnline

**Brief title**
MRI of the clitoral sexual arousal response (Clisek study)

### Condition

- Sexual function and fertility disorders

**Synonym**
sexual (dys)function, sexual (dys)functioning

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Amsterdam UMC

**Source(s) of monetary or material Support:** Stichting seksueel welzijn & COST European sexual medicine network

## Intervention

**Keyword:** Clitoris, Sexual arousal, Sexual response

## Outcome measures

### Primary outcome

The primary endpoint is clitoral volume during sexual arousal assessed by MRI

in healthy pre and postmenopausal women.

### Secondary outcome

Secondary endpoints are self-reported feelings of sexual arousal during

audiovisual sexual stimulation (erotic film), and sexual function assessed by a

validated sexual function questionnaire with the addition of items about

orgasmic functioning.

# Study description

### Background summary

Although the full anatomy of the clitoris was presented by O*Connell (O*Çonell et al. 1998), few people are aware of the three-dimensional structure of this organ, let alone of the exact size of the clitoris and its ability to become erect as a result of sexual arousal. Typical textbook descriptions of the clitoris lack detail and often include inaccuracies. Only a small number of scientific papers are available on size measurements and the increase in clitoral volume during sexual arousal. Moreover, there is a lack of research on the association of the clitoral sexual arousal response and sexual functioning. Population studies show that about 30% of women suffer from sexual dysfunctions, with a higher prevalence in postmenopausal women. It is not yet known how the clitoris size and ability to swell correlates with sexual functioning and if menopause influences the clitoris ability to swell during sexual arousal.

### Study objective

Primary Objective: The primary objective is to study clitoral volume changes during sexual arousal in premenopausal women compared to postmenopausal women.

Secondary Objective(s) are:
To study whether there is an association between feelings of sexual arousal during audiovisual sexual stimulation and clitoral volume or percentage change in clitoral volume during audiovisual sexual stimulation.
To study whether there is an association between self-reported sexual function and clitoral volume or percentage change in clitoral volume during audiovisual sexual stimulation.

**Study design**

This is an observational cohort case-control study with non-invasive measurements.

Participants receive questionnaires and magnetic resonance imaging (MRI) during watching of an erotic filmclip during a single occasion.

**Study burden and risks**

Changes in clitoral volume during sexual arousal in pre and postmenopausal women, and its association with sexual function is an understudied subject. Knowledge on clitoral responses during sexual arousal and possible pre and postmenopausal differences in clitoral volume will yield benefits for the general population in increasing knowledge on female sexual functioning facilitating female sexual pleasure and health, and for health professionals treating patients with sexual dysfunction.
The risks associated with this study are small: they are related to possible intruding questions on sexual arousal and discomfort associated with MRI testing. We think that a clear subject information sheet, as well as verbal explanation, should inform the subject sufficiently on the study procedures. Altogether, the set-up of our study allows us to collect unique information on clitoral volume changes during sexual arousal in pre and postmenopausal women. Connecting the experimental data to sexual function data, results in a positive balance of benefits as compared to the possible risks of this study.

# Contacts

**Public**
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ

NL
**Scientific**
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)

## Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Adult, >18 years of age
- Able to give written informed consent
- Having a primarily heterosexual orientation
- Having a stable, sexually active relationship for at least the preceding 6 months

In addition, for premenopausal women:
- Age < 45 and having a regular menstrual cycle.

In addition, for postmenopausal women:
- Age > 45 years, and no menstruation since at least one year, after a previously regular menstrual cycle. No use, or recent (in the prior 6 months) use of estrogen, hormonal medication, or hormonal contraception.

## Exclusion criteria

- Use, or recent (in the prior 6 months) use, of psychotropic medication
- Acute or chronic medical or mental conditions with a known effect on sexual

response
- Current pregnancy or delivery within the last 12 months
- History of hysterectomy or vaginal surgery, gynecologic disease or malignancy, pelvic inflammatory disease or vaginal infection and known anatomical abnormalities of the genitalia.
- Contra-indications to MRI (metal implants, pacemakers, claustrophobia, etc.).

# Study design

## Design

**Study type:** Observational non invasive

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

## Recruitment

NL

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| Recruitment status: | Completed |
| Start date (anticipated): | 20-01-2024 |
| Enrollment: | 24 |
| Type: | Actual |

# Ethics review

Approved WMO

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| Date: | 24-04-2023 |
| Application type: | First submission |
| 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 | NL83064.018.22 |