# A study of Outcome, Quality of Life and Satisfaction in women after breast reconstruction.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON22225

**Source**
Nationaal Trial Register

**Health condition**

Breast cancer, (preventive) mastectomy, BRCA gene mutation, Breast reconstruction, autologous reconstruction, alloplastic reconstruction.
Borstreconstructie, (preventieve) ablatio, , BRCA gen mutatie, autologe reconstructie, alloplastische reconstructie

### Sponsors and support

**Primary sponsor:** Univerity Medical Centre Groningen
**Source(s) of monetary or material Support:** sponsor

### Intervention

### Outcome measures

**Primary outcome**

The primary outcome measure is the Quality of Life as measured with the Breast Q.

### Secondary outcome

1. Health related Quality of Life as measured by the Rand 36;

2. The fear for recurrence of cancer on the QoL of the breast cancer patients as measured by the CARS;

3. Anxiety and Depression as measured by the HADS;

4. Cosmetic outcome as measured by the Strasser Score and the POSAS.

## Study description

### Background summary

Objective:

To systematically research the experiences concerning psychosocial impact and quality of life and their medical outcome of women who undergo different types of reconstruction. The results of this study may help to improve our insight into the effects of our work. With this knowledge we expect to be able to further improve the care for those patients. More specifically, this research aims to provide women who consider breast reconstruction with better counselling and help women make the best decision for an optimal treatment.

### Study objective

We expect that from 6 weeks on after a breast reconstruction with autologous material, quality of life is higher than after reconstruction with implants.

### Study design

The participants will fill in QoL questionnaires pre-operative and then at 6 weeks, 6 months, 1 year and 3 years post reconstruction.

### Intervention

For this study the main source for data are patient reported data, resulting from questionnairs.

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Women who have/had breast cancer and need(ed) a mastectomy and will undergo a breast reconstruction;

2. Women with BRCA gene mutation, who undergo a preventive mastectomy and want their breasts primarily reconstructed;

3. Young women with breast cancer who need preventive mastectomy of the other breast and want their breast reconstructed;

4. Informed consent.

## Exclusion criteria

1. Women who do not understand the Dutch language well;

2. Women who are illiterate in reading and/or writing;

3. Women below 18 years of age;

4. Women who are legally incompetent;

5. Women who have a bad prognosis. (terminally ill, patients with metastases);

6. Drug abuse.

# Study design

## Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Parallel |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-08-2012 |
| Enrollment: | 116 |
| Type: | Anticipated |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 18-07-2012 |
| Application type: | First submission |

# Study registrations

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

ID: 38410
Bron: ToetsingOnline
Titel:

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL3392 |
| NTR-old | NTR3534 |
| CCMO | NL32863.042.10 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |
| OMON | NL-OMON38410 |

# Study results

**Summary results**
N/A