

# The role of personality and quality of life (QOL) on morbidity, mortality, and health care consumption in breast cancer.

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|-----------------------------|---|
| <b>Ethische beoordeling</b> | Positief advies                                     |
| <b>Status</b>               | Werving gestart                                     |
| <b>Type aandoening</b>      | -   |
| <b>Onderzoekstype</b>       | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON21499

### Bron

Nationaal Trial Register

### Verkorte titel

N/A

### Aandoening

Personality

Breast cancer

Quality of Life

### Ondersteuning

**Primaire sponsor:** N/A

**Overige ondersteuning:** N/A

### Onderzoeksproduct en/of interventie

# Uitkomstmaten

## Primaire uitkomstmaten

1. The relationship between personality factors and prognosis in breast cancer patients<br>
2. The role of QOL and personality factors in the relationship between chemotherapy/radiotherapy/hormone therapy and morbidity (side-effects of treatment, fatigue, depressive symptoms, anxiety)<br>
3. The relationship between personality factors and health care consumption

## Toelichting onderzoek

### Achtergrond van het onderzoek

Although still a large percentage of breast cancer patients dies within five years after diagnosis, breast cancer has become a chronic disease instead of a live threatening cancer for many patients, possibly due to early detection through screening programs and to recent improvements in chemotherapy. Therefore, along with mortality, quality of life (QOL) has become an important endpoint of treatment. QOL refers to patients' evaluation of their functioning in a range of domains, such as physical, psychological, and social. A related concept that is frequently measured in breast cancer patients is health status (HS), i.e., patients' functioning. Studies have shown that both QOL and HS of breast cancer patients are impaired and predicted by morbidity, operationalized as fatigue, anxiety, and depressive symptoms. In addition, health care consumption was higher in breast cancer survivors. Apart from QOL and HS as endpoint of treatment, they have also been shown to predict morbidity, e.g., operationalized as rehospitalisation, and mortality.

Furthermore, personality, i.e., Type D, is recognized as important factor in cardiovascular diseases for morbidity and mortality. In breast cancer, trait anxiety has recently been found to play a role in QOL and depressive symptoms and fatigue. In addition, especially neuroticism has been examined in relation to HS, depression, anxiety, distress, and health care utilization in cancer. However, apart from the studies mentioned, personality factors have hardly been studied in breast cancer. Also, the role of QOL as predictor of morbidity, mortality, and health care consumption has not been examined in breast cancer. Therefore, the aim of the present study will be to examine the role of personality factors and QOL as predictors of morbidity (depressive symptoms (objective and subjective), fatigue, state anxiety (objective and subjective), arm and sexual problems, recurrence), mortality, and health care consumption in breast cancer patients above and beyond disease severity.

### Doel van het onderzoek

There is a relationship between personality factors and prognosis (i.e., mortality; recurrence of disease), also after correction for tumor staging.

Both personality and QOL play a role in the relationship between chemotherapy/radiotherapy

and morbidity (disease-specific side effects of treatment and symptoms; fatigue, depressive symptoms, state anxiety).

Personality factors and QOL predict the extent of health care consumption.

## **Onderzoeksopzet**

Questionnaires:

before diagnosis, and 1, 3, 6, 12, and 24 months after diagnosis.

## **Onderzoeksproduct en/of interventie**

There will be no interventio in this study, women who receive a diagnosis of breast cancer will be treated as usual.

Before diagnosis (BD) and 1, 3, 6, 12 and 24 months after diagnosis and treatment patients will complete a set of questionnaires; the WHOQOL-bref (QOL; BD, 12m, 24m), the STAI state (state anxiety; all timepoints) and STAI trait (trait anxiety; BD, 12m), the CES-D (depressive symptoms; all timepoints), the FAS (fatigue; all timepoints), the neuroticism part of NEO-FFI (neuroticism; BD, 12m), the DS14 (Type-D personality; BD, 12m), the LPM-Anx (psychological denial; BD), the CIDI (diagnostic interview; 12m) and the EORTC-QLQ-BR23 (health status, only breast cancer patients; 1m, 3m, 6m, 12m, 24m).

## **Contactpersonen**

### **Publiek**

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Women visiting for the first time the department of surgery of the participating hospitals with (a suspicion of) breast cancer.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Recurrence of disease at baseline
2. Poor expression in the Dutch language
3. Dementia
4. A history of psychiatric illness

## Onderzoeksopzet

### Opzet

Type: Observationeel onderzoek, zonder invasieve metingen  
Onderzoeksmodel: Anders  
**Controle:** N.v.t. / onbekend

### Deelname

Nederland  
Status: Werving gestart  
(Verwachte) startdatum: 01-05-2007  
Aantal proefpersonen: 600  
Type: Verwachte startdatum

## Ethische beoordeling

Positief advies

Datum: 24-11-2008

Soort: Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 31596

Bron: ToetsingOnline

Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID                                 |
|----------|------------------------------------|
| NTR-new  | NL1485                             |
| NTR-old  | NTR1555                            |
| CCMO     | NL15659.008.06                     |
| ISRCTN   | ISRCTN wordt niet meer aangevraagd |
| OMON     | NL-OMON31596                       |

## Resultaten

### Samenvatting resultaten

N/A