

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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21499

Source

Nationaal Trial Register

Brief title

N/A

Health condition

Personality
Breast cancer
Quality of Life

Sponsors and support

Primary sponsor: N/A

Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

1. The relationship between personality factors and prognosis in breast cancer patients

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)
3. The relationship between personality factors and health care consumption

Secondary outcome

The stability of personality factors

Study description

Background summary

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 life 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.

Study objective

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.

Study design

Questionnaires:

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

Intervention

There will be no intervention 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).

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type: Observational non invasive

Intervention model: Other

Control: N/A , unknown

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-05-2007

Enrollment: 600

Type: Anticipated

Ethics review

Positive opinion

Date: 24-11-2008
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 31596
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results

N/A