

The influence of personality, anxiety and surgical treatment on quality of life in early stage breast cancer.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26378

Source

Nationaal Trial Register

Brief title

N/A

Sponsors and support

Primary sponsor: none

Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

1. Quality of life over time in breast cancer patients;
2. The influence of surgical treatment and personality.

Secondary outcome

1. Quality of life over time in breast cancer patients compared to patients with a benign breast disease;

Study description

Background summary

PURPOSE: The aim of this trial is to examine the role of patients' personality on the relation between type of surgery and quality of life. It is hypothesized that breast cancer patients high on trait anxiety who get a breast conserving operation will subsequently have a lower QoL compared with high trait anxiety patients who receive a modified radical mastectomy, because they will worry about recurrence of cancer in the treated breast. The underlying goal is to provide women who may choose between a modified radical mastectomy and a breast conserving therapy an advise concerning their decision.

One in every nine women in the Netherlands will develop breast cancer during her life. For early stage breast cancer, ablative therapy (being either a modified radical mastectomy (MRM) or an ablation of the breast with a sentinel node procedure) and breast conserving therapy (BCT) (i.e., a lumpectomy with an axillary lymph node dissection or a sentinel node procedure followed by radiotherapy) are comparable concerning overall survival. Disease-free survival is significantly shorter in patients with BCT, but recurrent cancer does not influence the overall survival. Due to early detection through screening programs and possibly by improved adjuvant treatment, for most patients breast cancer has become a chronic disease rather than a life threatening disease. Therefore, quality of life (QoL) is becoming increasingly important. Our prospective, longitudinal preliminary study has shown that trait anxiety rather than other personality characteristics (i.e., neuroticism, extraversion, openness to experience, agreeableness, conscientiousness) determines the QoL of both breast cancer patients and benign patients, at least until six months after surgical treatment (see Preliminary results). Trait anxiety appears to have a devastating effect on QoL. To get further insight in the relationship between trait anxiety and QoL, we want to examine whether the interaction between trait anxiety and type of surgery, i.e. BCT or MRM, also plays a role in patients' QoL.

Patients with a first event of a palpable lesion in the breast or a suspect lesion on a screening mammography are eligible for inclusion. Prior to diagnosis and 1-3-6-12-24 months after diagnosis and possible treatment a set of questionnaires will be completed. Participation in the study is not known to the treating surgeon and will have no influence on the decisional process concerning surgical treatment.

Study objective

Patients with high scores on anxiety and neuroticism will experience a lower Quality of Life after breast conserving therapy compared to modified radical mastectomy.

Intervention

There will be no interventions in surgical treatment. Patients will choose surgical treatment together with their treating surgeon. This choice is based on international guidelines for early stage breast cancer and on personal preferences of the patient.

Before diagnosis and 1-3-6-12-24 months after diagnosis and treatment patients will complete a set of questionnaires. These questionnaires will be the WHOQOL-100 (quality of life questionnaire), the STAI (state and trait anxiety questionnaire), the CES-D (questionnaire concerning depressive symptoms), the FAS (questionnaire concerning fatigue) and the NEO-FFI (a personality questionnaire; only completed before diagnosis).

Contacts

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Eligibility criteria

Inclusion criteria

All women with a first event of a palpable lesion in the breast or a abnormal screening mammography.

Exclusion criteria

1. Breast cancer in the medical history;
2. Dementia;
3. T3 or T4 tumours;
4. Unable to read or write Dutch.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2002
Enrollment:	500
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

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

NTR-new

NTR-old

Other

ISRCTN

ID

NL424

NTR464

: N/A

ISRCTN01021331

Study results

Summary results

N/A