

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

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

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26378

Bron

Nationaal Trial Register

Verkorte titel

N/A

Ondersteuning

Primaire sponsor: none

Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Breast cancer in the medical history;
2. Dementia;
3. T3 or T4 tumours;

4. Unable to read or write Dutch.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-09-2002
Aantal proefpersonen:	500
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL424
NTR-old	NTR464
Ander register	: N/A
ISRCTN	ISRCTN01021331

Resultaten

Samenvatting resultaten

N/A