

The psychosocial determinants of stress(vulnerability) and cognitive complaints in breast cancer patients receiving elective radiotherapy

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The primary aim of this study is to identify the psychosocial determinants of stress (vulnerability) and cognitive complaints in breast cancer patients treated with adjuvant radiotherapy. The stress model of Taylor and Aspinwall will be used.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational non invasive

Summary

ID

NL-OMON31975

Source

ToetsingOnline

Brief title

Cognitive complaints after elective radiotherapy for breast cancer

Condition

- Miscellaneous and site unspecified neoplasms benign
- Cognitive and attention disorders and disturbances
- Breast disorders

Synonym

breast cancer; breast carcinoma

Research involving

Human

Sponsors and support

Primary sponsor: TweeSteden ziekenhuis

Source(s) of monetary or material Support: Geen financiering

Intervention

Keyword: cancer, cognition, radiotherapy, stress

Outcome measures

Primary outcome

Subjective cognitive complaints

Secondary outcome

n.a.

Study description

Background summary

Several studies have found cognitive impairment in subgroups of patients treated with chemotherapy, based on data of predominantly breast cancer patients. Studies on cognitive sequelae of radiotherapy are scarce, but show that cognitive complaints can also occur after this treatment modality. No correlation has been found between cognitive impairment scores en cognitive complaints. Cognitive complaints were related to anxiety and depression scores. Little is known about the psychosocial predictors of cognitive complaints and the relationship with stress-vulnerability in breast cancer patients.

Study objective

The primary aim of this study is to identify the psychosocial determinants of stress (vulnerability) and cognitive complaints in breast cancer patients treated with adjuvant radiotherapy. The stress model of Taylor and Aspinwall will be used.

Study design

Women with a palpable lump in the breast visiting the TweeSteden Hospital (Tilburg) during the period May 2008 and January 2011, are asked to participate in the study. They all complete questionnaires at baseline. Only women, who are

diagnosed with breast cancer and receive elective radiotherapy participate further in the study. Completion of questionnaires (demographic factors, personality factors (only at baseline), self esteem, depressive symptoms, anxiety, fatigue, social support, perceived stress and coping) will occur before diagnose and 3, 6 and 12 months after ending radiotherapy. Patients fill in the questionnaires at home. Data will be analyzed with univariate regression analyses (ANOVA, ANCOVA). With an alpha set at 0.05 and a power of .80 a sample size of 77 is needed. A large effect size is tolerated.

Possible results: This study can provide more insight in the relationship between a life threatening disease i.e. breast cancer, relevant psychosocial factors, stress (vulnerability) and subjective cognitive complaints. Patients can be provided with information relating experienced cognitive problems to emotional distress and subsequent interventions can address a patient's specific stressors and promote effective coping strategies.

Study burden and risks

n.a.

Contacts

Public

TweeSteden ziekenhuis

Postbus 90107
5000 LA Tilburg
NL

Scientific

TweeSteden ziekenhuis

Postbus 90107
5000 LA Tilburg
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Women, who are for the first time diagnosed with breast cancer and receive elective radiotherapy.

Exclusion criteria

Alcohol- or drugs abuse

No Dutch speaking

Radio- or chemotherapy before

Neurological or psychiatric history

Medication that can influence cognitive functioning

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-05-2008

Enrollment: 77

Type: Anticipated

Ethics review

Approved WMO

Application type:

First submission

Review commission:

METC Brabant (Tilburg)

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	ID
CCMO	NL22005.028.08