Fear of recurrence at breast cancer patients: "Is the FCRI (Fear of Cancer Related Inventory) a reliable and valid questionnaire for assessing fear of cancer recurrence?"

Published: 21-06-2011
Last updated: 29-04-2024

The primary aim of the study is to develop the Dutch version of the FCRI (Fear of Cancer Related Inventory)

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational non invasive

Summary

ID

NL-OMON35859

Source
ToetsingOnline

Brief title
Fear of recurrence at breast cancer patients

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, breast neoplasm

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Breast Cancer, Fear of recurrence, Questionnaire, Validation

Outcome measures

Primary outcome

The Dutch version of the FCRI, that is reliable and a valid questionnaire for

assessing fear of cancer recurrence

Secondary outcome

N.A.

Study description

Background summary

Fear of disease recurrence (FOR) is a common concern among cancer patients. The fear of cancer recurrence (FCR) is the most long-term psychological consequences of surviving cancer and it is persist long after the termination of treatment. In this study, we used the FCR definition made by Vickberg et al. : the fear or worry that the cancer will return or progress in the same organ or in another part of the body. There is not a standard fear of recurrence (FOR) used in the majority of studies. Several studies used a single question or a few items to examine FOR. Simard and Sarvard provided a short overview of existing FOR questionnaires. Some questionnaires have been specifically developed for breast cancer patients, such as the Concerns About Recurrence Scale (CARS). The CARS is the only questionnaire that has been translated and validated in Dutch for investigate FOR. Only the problem is that the CARS not incorporated all relevant dimensions of FCI. This was the main reason for developing the Fear of Cancer Related Inventory (FCRI). The FCRI that assesses seven factors (triggers, severity, psychological distress, coping strategies, functioning impairments, insight and reassurance) is the only measuring that incorpates ways patients cope with FOR. It is important to assess this aspect because the way patients cope with FOR will determine the amount of psychological distress that patients will experience. A disadvantage of the

FCRI is that it is developed and validated in Canada among a heterogeneous cancer population, of which one third had breast cancer.

Study objective

The primary aim of the study is to develop the Dutch version of the FCRI (Fear of Cancer Related Inventory)

Study design

The first part consists of developing the Dutch version of the FCRI using the standard translation method of the WHOQOL instruments, which is based on the WHO guidelines, and running focus groups. Participant for the focus groups (N=30) will be recruited by health professionals working in the hospital. Once the health professional has obtained the patient*s permission to be approached by the student, this student will phone the patients. Further information about this part of the study will be given by phone, and when they still interested, they receive a written document with comprehensive information about the study, explaining the aims and procedures of the focus group meetings. Based on the result of the focus groups, the Dutch FCRI is adapted.

For the validation of the Dutch version of the FCRI, the other patients will subsequently receive a letter explaining the purpose of the study and asking them to participate. Patients also receive an informed consent form. When the patient give permission they receive a set of questionnaires and the signed informed consent form. One hundred long-term survivors (end of treatment at least 2 years ago) will be asked to complete the FRCI twice with an interval of 1 months to examine test-retest reliability.

The set of questionnaires for the validation part of this study consist of seven questionnaires examining:
• FOR (Dutch version of the FCRI and CARS-DLV)
• Depressive symptoms and anxiety (CES-D and STAI state scale)
• Coping strategies (CISS), QOL (WHOQOL-Bref)
• Trait anxiety (STAI trait scale)

A sample size of 75 patients is sufficient to test the construct validity (Pearson correlations will be calculated between the Dutch FCRI and the other questionnaires).
A sample size of 400 patients is sufficient to test the structure of the FCRI (confirmatory factor analysis (AMOS 4.0)).

Study burden and risks

N.A.

Contacts

Public
Sint Elisabeth Ziekenhuis

Hilvarenbeekseweg 60
5022 GC Tilburg
NL
Scientific
Sint Elisabeth Ziekenhuis

Hilvarenbeekseweg 60
5022 GC Tilburg
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Women who where treated for breast cancer in the St. Elisabeth hospital (Tilburg) between January 2000 and September 2010 and who are still alive.

Exclusion criteria

disease recurrence or metastases at baseline; history of neuropsychologic and/ or psychiatric signs or symptoms that lead to deviant neuropsychologic test results (e.g. dementia); the use of medication that may lead to deviant neuropsychological results; alcohol and drug addiction; poor expression in the dutch language

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-07-2011
Enrollment:	505
Type:	Actual

Ethics review

Approved WMO

Date:	21-06-2011
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	NL37119.008.11