Experiences and health care needs of women with breast cancer. [Ervaringen en behoefte aan zorg van vrouwen met borstkanker.]

No registrations found.

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

Summary

ID

NL-OMON23929

Source
NTR

Brief title
PINK DIAMOND

Health condition

borstkanker, mammacarcinoom,
breast cancer

Sponsors and support

Primary sponsor: Department of Medical Psychology Academic Medical Centre
The Netherlands
Source(s) of monetary or material Support: Pink Ribbon

Intervention

Outcome measures

Primary outcome

1. Health care needs;

2. Health care use;

3. Health care costs and work-loss costs of breast cancer patients.

Secondary outcome

N/A

Study description

Background summary

Rationale:

Being confronted with breast cancer may fundamentally disrupt a patient's life. Newly diagnosed women may experience such elevated distress during or shortly after treatment that referral to psychosocial health care services is warranted. In the long term, breast cancer survivors do not differ from same-age controls of the general population with respect to health status and psychological wellbeing. Nevertheless, breast cancer survivors use more health care services than women from the general population. Additionally, breast cancer patients have more health care costs and work-loss related costs than women from the general population.
The literature on health care use and costs of breast cancer patients is limited. Specifically, it has yet to be determined whether breast cancer patients with clinically relevant levels of psychosocial distress receive the health care they need. Additionally, research is needed to identify breast cancer patients who likely require more extensive health care, and for whom costs will be high. The current project examines associations between distress, health care needs, use, costs and characteristics of breast cancer patients at two points in time: 6 months after diagnosis, and 15 months after diagnosis. This information may be used to tailor psychosocial health care, which may reduce breast cancer patients' overall health care needs, use, and costs.

Primary objective:

To investigate the association between the psychosocial distress levels of breast cancer patients and their concurrent and future health care needs, health care use, individual health care costs and work-loss costs, as determined at two points in time: 6 months, and 15 months after diagnosis.

Secondary objectives:

1. To document prevalence of and changes in distress levels, distress-related problems, health care needs, use, and costs of breast cancer (assessed 6 months, and 15 months after diagnosis);

2. To determine the extent to which sociodemographic variables, psychological characteristics, enabling, clinical and psychosocial factors are associated with health care needs, use, and costs of breast cancer patients at the two points in time;

3. To determine which health care services should be available to fulfil breast cancer patients' needs at the two points in time.

Country of recruitment: The Netherlands.

Study objective

We hypothesize that higher distress levels will be associated with higher perceived need for and actual use of health care services, and with higher individual health care and work-loss related costs.

Study design

6 months after diagnosis and 15 months after diagnosis.

Intervention

A prospective, multicenter, observational study will be carried out in nine medical centers in the Netherlands. In each center, 100 breast cancer patients will be asked to fill in a questionnaire via the internet or by mail at two points in time, 6 months and 15 months after diagnosis.

The questionnaire will measure sociodemographic and clinical background characteristics, psychosocial distress, perceived health care needs, use of health services, and costs. Additional clinical data will be retrieved via medical record audits.

Contacts

Public
Department of Medical Psychology
Academic Medical Centre
Meibergdreef 15

D. Lo-Fo-Wong
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5667112
Scientific
Department of Medical Psychology
Academic Medical Centre
Meibergdreef 15
D. Lo-Fo-Wong
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5667112

Eligibility criteria

Inclusion criteria

All newly diagnosed adult female breast cancer patients with primary mamma carcinoma who visit one of nine participating centers are eligible for this study.

Patients may be included up to 6 months after diagnosis, regardless of disease stage or type of treatment.

Exclusion criteria

Patients will be excluded if they:

1. Are younger than 18 years;

2. Are not literate in Dutch;

3. Have a prognosis of 3 months or less;

4. Have recurrent breast cancer.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-02-2011
Enrollment:	900
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-07-2011
Application type:	First submission

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
NTR-new	NL2843
NTR-old	NTR2985

Register	ID
Other	MEC AMC : 09.17.1591
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A