

# Experiences and health care needs of women with breast cancer.

## [Ervaringen en behoefte aan zorg van vrouwen met borstkanker.]

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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.

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Observationeel onderzoek, zonder invasieve metingen

### Samenvatting

#### ID

NL-OMON23929

#### Bron

NTR

#### Verkorte titel

PINK DIAMOND

#### Aandoening

borstkanker, mammacarcinoom,  
breast cancer

#### Ondersteuning

**Primaire sponsor:** Department of Medical Psychology Academic Medical Centre  
The Netherlands

**Overige ondersteuning:** Pink Ribbon

#### Onderzoeksproduct en/of interventie

# Uitkomstmaten

## Primaire uitkomstmaten

1. Health care needs;<br>
2. Health care use;<br>
3. Health care costs and work-loss costs of breast cancer patients.

## Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### **Doel van het onderzoek**

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.

### **Onderzoeksopzet**

6 months after diagnosis and 15 months after diagnosis.

### **Onderzoeksproduct en/of interventie**

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.

## **Contactpersonen**

### **Publiek**

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## **Wetenschappelijk**

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## **Deelname eisen**

### **Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)**

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.

### **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

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.

## Onderzoeksopzet

### Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
<b>Controle:</b>	N.v.t. / onbekend

### Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	05-02-2011
Aantal proefpersonen:	900
Type:	Verwachte startdatum

## Ethische beoordeling

Positief advies	
Datum:	13-07-2011
Soort:	Eerste indiening

## 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**

NTR-new

NTR-old

Ander register

ISRCTN

**ID**

NL2843

NTR2985

MEC AMC : 09.17.1591

ISRCTN wordt niet meer aangevraagd.

## Resultaten

**Samenvatting resultaten**

N/A