

A randomized trial to assess the (cost) effectiveness of the discussion of the distress thermometer by a nurse in addition to usual care for patients treated with curative intent for breast cancer

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An efficiency study will be conducted to evaluate the systematic use of the distress thermometer and its discussion by a nurse as compared to the usual care provided to outpatients who are treated for primary breast cancer by their treating...

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

Summary

ID

NL-OMON32495

Source

ToetsingOnline

Brief title

Nurse Intervention Project

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Anxiety disorders and symptoms
- Breast therapeutic procedures

Synonym

psychosocial problems and distress

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Pink ribbon

Intervention

Keyword: breastcancer, distress, lastmeter, psychosocial care

Outcome measures

Primary outcome

Subscale quality of life of the questionnaire: EORTC QLQ C30.

Secondary outcome

Other subscalea of the EORTC QLQ C30 and the questionnaires: HADS, EORTC BR23, SVL, ZCL.

Study description

Background summary

Every year about 90,000 people are diagnosed with cancer in the Netherlands. Despite the increasing survival, cancer still has a major impact on someone's life. Patients experience psychosocial distress after hearing diagnosis, during treatment and if the disease relapses. The use of interventions for cancer-related distress is important to reduce this distress. Distress has a negative impact on the quality of life, the recovery during and after treatment and may even adversely affect survival. There is insufficient attention to the systematic approach to psychosocial problems in cancer patients in the Netherlands. A task force discussed and studied which instrument measures psychosocial problems best. The lastmeter (distress thermometer) had the best results. A guideline is written to use the lastmeter for patients with cancer and will be used in hospitals in the Netherlands. However, it is not clear what the effects are of the use of the lastmeter on the psychosocial wellbeing of the patient. Furthermore, it is also unknown whether the use of the lastmeter leads to cost-effective care. This study focuses on breast cancer patients. Patients with breast cancer are often relatively young, the treatment process

is lengthy and they have a long survival expectancy. Therefore, it is important to optimize the psychosocial care so long term problems can be avoided. A study on the application of the lastmeter for this patient group is thus of importance. The research question is: what is the effect of discussion the lastmeter by a nurse on the psychosocial well-being in patients treated for primary breast cancer?

Study objective

An efficiency study will be conducted to evaluate the systematic use of the distress thermometer and its discussion by a nurse as compared to the usual care provided to outpatients who are treated for primary breast cancer by their treating physicians . The clinical and economic impact of the use of the lastmeter will be assessed in comparison with usual care.

Study design

A RCT with two arms will be performed.

Intervention

The intervention is to apply the distress thermometer as written in the guideline written by 'Vereniging Integrale Kankercentra'. The distress thermomter is collected from the experimental group and then discussed by a trained nurse.

Study burden and risks

There is no risk associated with this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- histologically proven malignancy of the breast
- curative treatment
- dominated the dutch language
- Age > 18 year

Exclusion criteria

- Previously treated for a malignancy
- Psychiatric problems that adherence this study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-03-2010
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO	
Date:	18-01-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL30169.091.09