Prognostic disclosure in the palliative phase of breast cancer: Quality of communication from a patient perspective.

Published: 23-03-2010
Last updated: 30-04-2024

The aim of this project is to determine optimal communication strategies for prognostic disclosure in the palliative phase of breast cancer from a patient perspective. Study 1: To explore breast cancer survivors*, healthy women*s and oncologists*…

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

Summary

ID

NL-OMON36591

Source
ToetsingOnline

Brief title
Prognostic disclosure in the palliative phase of breast cancer.

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, maligne mamma-carcinoom

Research involving
Human

Sponsors and support

Primary sponsor: NIVEL

Source(s) of monetary or material Support: Spinoza prijs Prof. dr. J. M. Bensing

Intervention

Keyword: (breast) cancer, analogue patients, communication, palliative care

Outcome measures

Primary outcome

Study 1: Qualitative data - opinions concerning the disclosure of a palliative prognosis and the role of hope and explicitness herein.

Study 2: Experiment: anxiety- and uncertainty reduction

Add-on study: Emotional arousal and recall are the main study parameters of this pilot study. Emotional arousal will be measured with physiological responses (heart rate and skin conductance). Recall is assessed as the number of correctly recognized or recalled information elements (both primed and free recall) will be measured.

Secondary outcome

Study 2: Experiment: satisfaction, self efficacy

Focusgroups: qualitative data - opinions concerning the specific communication elements.

Add-on study: same as main study. Extra: positive & negative affect.

Study description

Background summary

Good communication is essential in health care, especially in sensitive areas such as the transition from curative to palliative cancer care. A palliative breast cancer diagnosis evokes both feelings of uncertainty and anxiety, at which oncologists have to react. While all patients want to be aware of their disease*s terminal nature, how explicit versus general oncologist should be in their prognostic information is still unknown. In addition, the need for hope persists for all cancer patients, at the same time as the need for realistic information. But what comprises hope is still unknown and an empirical base for its beneficial effect is lacking.. So far, experimental studies of communication in a cancer consultation have not been the focus in much research for several reasons. First, it is methodologically difficult to create a state of the art randomized controlled trial in the clinical setting because it is unethical to expose clinical patients to possibly harmful communication. Second, communication is often used as a container concept with little focus on the specific elements it consists of. To overcome these and other problems and to study the effect of explicit opposed to general prognostic information and expressed hope opposed to realism on patients* feelings of anxiety and uncertainty about their future, an experimental study has been created, which uses healthy subjects and breast cancer survivors instead of clinical patients. Research also shows that receiving bad news causes stress and patients often do not remember much of the information provided in bad news consultations. Therefore an add-on study will be carried out in order whether certain affective communication can cause a decrease in physiological arousal and consequently an increase in recall of information provided in a bad news consultation.

Study objective

The aim of this project is to determine optimal communication strategies for prognostic disclosure in the palliative phase of breast cancer from a patient perspective.
Study 1: To explore breast cancer survivors*, healthy women*s and oncologists* opinions on which topics they consider important when discussing a palliative prognostic disclosure and how oncologists can trade the fine lines between providing general as opposed to explicit information and realistic as opposed to hopeful information when discussing these topics.
Study 2: To determine the main and interaction effects of the levels of explicitness of information and expressed hope when providing prognostic disclosure in palliative breast cancer, using a systematic controlled study design. Mediating and moderating effects of optimism and coping (monitoring/blunting) will be analyzed.
Add-on study: The objective of this pilot study is to explore in an experimental design whether various styles of communication in a bad news consultation have a differential effect on patients* emotional arousal and recall of provided information. In particular, we want to explore the role of affective communication.

Study design

Study 1: Focus groups (for breast cancer survivors and healthy subjects) and semi-structured interviews (for oncologists).
Study 2: Self created, standardized videos in which the level of explicitness of information and expressed hope are systematically varied will be shown to healthy subjects and breast cancer survivors to assess the elements* impact on their perceptions. A subsample of the subjects will participate in focus groups to provide qualitative information about their opinions concerning the varied communication elements.
Add-on study: Women will be randomized to watch one out of two videotaped bad news consultations which are identical in the amount and content of the provided information but differ in physician*s communication style. Physiological arousal during watching the video and recall of provided information will be assessed.

Intervention

Stuy 1: observation-design: focus groups and interviews
Study 2: experiment: 4 video-vignettes are viewed .
Add-on study: 1 video-vignette is viewed.

Study burden and risks

Studie 1 + 2: Breast cancer survivors: It can be a burden for breast cancer survivors to think about or look at videos of a prognostic disclosure in palliative cancer care. So, we will only recruit members of the Dutch Breast Cancer Organisation and have a clinical psychologist available for support.
Healthy women: It can be disturbing for healthy subjects to think about or look at videos of a prognostic disclosure in palliative cancer care, especially if they experienced a similar consult in their immediate personal network. No risk.

Contacts

Public
NIVEL

Otterstraat 118-124
Postbus 1568, 3500 BN Utrecht
NL
Scientific
NIVEL

Otterstraat 118-124
Postbus 1568, 3500 BN Utrecht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Study 1 + 2: breast cancer survivors: women between 18-65, minimally 5 years disease-free, speak fluent Dutch, members of Dutch Breast Cancer Organisation.
healthy women: women between 18 and 65, speak fluent Dutch.
add-on study: healthy women between 18-65, fluent in Dutch

Exclusion criteria

Study 1 + 2: breast cancer survivors: less than 5 years disease free.
healthy women: women who are cancer survivors.;Add-on study: women who are cancer survivors.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-05-2010
Enrollment:	330
Type:	Actual

Ethics review

Approved WMO Date:	23-03-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	05-07-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	15-02-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-07-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL29968.041.10