Sexual and relationship healthcare evaluation among women with breast cancer and their partners

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON45495

Source
ToetsingOnline

Brief title
SIREN BC

Condition

- Other condition

Synonym
breastcancer patients, intimacy, relationship quality, sexual dysfunction, sexual health

Health condition

psychooncology

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: breast cancer, intimacy, relationship, Sexual health

Outcome measures

Primary outcome

- To obtain an insight in the need and perspective of female breast cancer

patients on sexual healthcare provided by care providers.

Secondary outcome

- To determine patients* point of view on which care provider should be

accountable for providing sexual healthcare

- To determine patients* point of view on type and timing of sexual healthcare

- To collect information on partner* perspective and opinions on sexual

healthcare provided by care providers .

- To collect information on the influence of the diagnosis breast cancer,

sexual dysfunction, and treatment on relationships

Study description

Background summary

Women who are diagnosed and treated for breast cancer often experience difficulties with intimacy and sexuality. Unfortunately, sexual health and intimacy remain difficult subjects to discuss and are often ignored by healthcare providers. Furthermore, little is known about patients' need and perspective on healthcare regarding sexuality and intimacy. Even less is known about the impact of breast cancer, treatment, and sexual issues on the relationship between patient and partner and how these factors impact partner'

well-being.

Study objective

The aim of our multicenter study will be to evaluate breast cancer (BC) patients* perspective on sexual healthcare currently provided by oncology care providers. Furthermore we will identify patients* wishes and views upon this important part of oncology healthcare and the impact of BC and SD (sexual dysfunction) on relationships. Partners will be included as they suffer from the effects of BC on patients* sexuality as well.

Study design

Data for this cross-sectional multi-centre survey will be collected among women who were diagnosed with and treated for non-invasive or invasive BC in the past two years at University Leiden * The Hague Cancer Center (Leiden University Medical Center en Haaglanden Medical Center) and Groene Hart Hospital Gouda.Two different questionnaires will be used; one evaluating patients* perspective and one evaluating the perspective of the partners. Structure and design of these questionnaires were derived from questionnaires used in previous studies performed by our research institute. These questionnaires were designed to evaluate sexual healthcare and impact of disease, sexual dysfunction, and treatment on relationships. Data will be processed an analysed anonymously.

The Groene Hart Hospital (Gouda) and Alrijne Hospital (Leiderdorp) will also participate in this study. Their participation will be announced later on through an amendement, since some acquired documents for their participation are not yet completed.

Study burden and risks

Patients will receive an information letter by post, explaining the objectives of the study. An informed consent form will be added with this letter. Participation can be considerate at home, without any haste. If consent is provided, a questionnaire will be send to the respondents. It concerns a patient (and partner) survey with sensitive questions

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2 Albinusdreef 2
Leiden 2300RC

NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2 Albinusdreef 2
Leiden 2300RC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Women who were diagnosed with and treated for non-invasive or invasive breast cancer in the past two years at University Leiden * The Hague Cancer Center and Groene Hart Hospital Gouda
- Partners of women who were diagnosed with and treated for non-invasive or invasive breast cancer in the past two years at University Leiden * The Hague Cancer Center and Groene Hart Hospital Gouda
- Age older than 18 years
- Patients and/or partners must consent in order to be included in the study
- Ability to understand a questionnaire in Dutch

Exclusion criteria

- Patients who are mentally incompetent to give informed consent
- Age under 18
- Patients who passed away
- Patients who moved abroad
- Male breast cancer patients
- Patients with a benign breast tumour

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2017
Enrollment:	1570
Type:	Actual

Ethics review

Approved WMO

Date:	19-01-2017
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO

Date:	10-03-2017
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL59884.058.16