

Kwaliteit van communicatie in de spreekkamer.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23927

Source

NTR

Health condition

- breast cancer
- shared decision making
- quality improvement
- patient preferences
- patient participation

Sponsors and support

Primary sponsor: Universiteit Maastricht

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

Intervention

Outcome measures

Primary outcome

- Knowledge on treatment
- Perceived shared decision making

- Decisional conflict

Secondary outcome

Patients and caregivers experiences with implementation of shared decision making and the patient decision aid.

Study description

Background summary

Background and aim

The majority of patients diagnosed with early stage breast cancer are eligible to decide between having a mastectomy or lumpectomy with radiation (breast conserving therapy). The long term survival for mastectomy versus lumpectomy and radiotherapy is comparable, therefore patients' informed preferences are important in the decision making. Although most clinicians believe they involve patients in the decision making process, the information that women with breast cancer receive regarding the surgical options in breast cancer is often colored. Shared decision making can help patients to clarify their preferences. Patient decision aids support shared decision making.

The aim of this study is to pilot-test and optimize strategies for implementation of shared decision making on the treatment of early-stage breast cancer in the true clinical setting.

Methods/Design

This study concerns a pre-post pilot implementation study, carried out from October 2014 to June 2015. The intervention consists of implementing shared decision making (SDM) using a patient decision aid. The intervention will be evaluated using qualitative and quantitative measures, acquired prior to, during and after the implementation of SDM. Outcome measures are knowledge on treatment, perceived shared decision making and decisional conflict. We also will also conduct face-to-face interviews with a purposeful sample of these patients and their caregivers to assess their experiences on implementation of shared decision making and the patient decision aid.

Discussion

The outcomes and findings of this study will be used as a basis to finalise a multi-faceted implementation strategy with the intention to test the implementation of shared decision

making and a patient decision aid on cost-effectiveness in a multicentre cluster RCT.

Country of recruitment: The Netherlands.

Study objective

With a multi-faceted strategy we are able to implement shared decision making so that it meets the needs and demands of both professionals and patients, without interfering in daily practice.

Study design

- Knowledge on treatment and perceived shared decision making are measured immediately after intervention.
- Decisional conflict is measured two months after treatment.
- Patients and caregivers experiences are measured within three months after the implementation.

Intervention

Implementing shared decision making (SDM) using a patient decision aid.

Contacts

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Eligibility criteria

Inclusion criteria

Patients diagnosed with stage I or II breast cancer, provided the two treatment options, mastectomy or breast conserving surgery with radiotherapy, are applicable. Eligible patient should speak and understand the Dutch language.

Exclusion criteria

- Men diagnosed with breast cancer
- Women not eligible to decide between having a mastectomy or lumpectomy with radiation.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-10-2014
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date: 05-11-2014
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	NL4751
NTR-old	NTR4879
Other	Pink Ribbon : 2012.PS23

Study results