

Protocol implementation of Shared Decision Making in Dutch breast cancer care; a prospective process evaluation

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27250

Source

NTR

Health condition

Breast cancer
Shared decision making
Implementation
Decision aid
Patient communication

Borstkanker
Gezamenlijk beslissen
Keuzehulpen
Implementatie
Patient communicatie

Sponsors and support

Primary sponsor: Trudy.vanderweijden@maastrichtuniversity.nl

Source(s) of monetary or material Support: KWF Ad6

Intervention

Outcome measures

Primary outcome

With respect to our hypotheses on frequency of registering indication for a patient decision aid in the Multidisciplinary Board, for handing out and actually logging in, and assuming that that we can include 150 patients in total (5 hospitals, 30 patients per hospital), we expect that:

- in 120 patients the indication for the decision aid is registered in the Multidisciplinary tumor board, i.e. in 80%, with a 95% CI of 74-86%.
- in 105 patients the personalized decision aid will be handed out, i.e. in 70% with a 95% CI of 63-77%.
- 90 patients will actually log in to the patient decision aid, i.e. 60% with a 95% CI of 53-67%.

Secondary outcome

Evaluation experiences professionals of applying the Shared Decision Making and the use of the decision aid

Study description

Background summary

Rationale: Practice variations in treatment of early-stage breast cancer should be determined by the preferences of well-informed patients. There is, however, substantial practice variation in type of surgery in breast cancer between Dutch hospitals. Involving patients in the decision making process is seen as an important strategy to reduce unwarranted variation in preference-sensitive care. In an earlier study, we developed a personalized patient decision aid, which was pilot tested in 4 hospitals. Based upon this pilot test, we adapted the implementation strategy. Currently, the decision aid is being implemented in the hospitals in the OncoZON region, and in the hospitals that had participated in the pilot study.

Objectives: The main aim of the current study is to further investigate implementation challenges, by investigating the actual implementation rate at several levels, by investigating barriers and facilitators for implementation, and by investigating patient-experiences on shared decision making.

Study design: This study concerns an observational study, a prospective process evaluation of the implementation of the decision aid.

Study population: Patients with newly diagnosed breast cancer, stage I or II who are eligible for breast conserving therapy or mastectomy can be included. We expect that 5 hospitals will each include 30 patients in a period of 6 months. In addition, in each hospital, all breast surgeons, medical oncologists, radiation oncologists, reconstructive surgeons, nurse practitioners and nurses taking part in the education and decision-making process are invited to participate in implementation of SDM.

Study design

Audits and interviews: immediately after implementation

Patient questionnaires: during implementation.

Intervention

The intervention consists of offering patients a personalized patient decision aid.

Contacts

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Eligibility criteria

Inclusion criteria

Patients with newly diagnosed breast cancer, stage I or II who are eligible for breast conserving therapy or mastectomy

Exclusion criteria

Not understanding the Dutch language

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-05-2016
Enrollment:	150
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

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	NL5614
NTR-old	NTR5721
Other	KWf Ad6 shared decision making : 2014-7024

Study results