Implementation and evaluation of shared decision-making for breast cancer follow-up care

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22492

Source
Nationaal Trial Register

Brief title
SHOUT-BC

Health condition

Breast cancer

Sponsors and support

Primary sponsor: Santeon
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Patients' perceived level of involvement in the decision-making process (using the SDM-Q-9).

Secondary outcome

Patients' involvement in the decision-making process from the observers' viewpoint (using the OPTION-5).

Study description

Background summary

The primary objectives are to assess the effectiveness of shared decision-making supported by outcome data; alongside its implementation in daily clinical practice. The secondary objectives are to assess the extent to which shared decision-making supported by outcome data leads to changes in the utilisation and outcomes of healthcare.

Study objective

Successful implementation of a patient decision aid regarding breast cancer follow-up care facilitates shared decision-making and results in quality improvement in breast cancer follow-up care.

Study design

In total, seven hospitals will participate in this trial for 20 months. In the first 6 months we will assess daily clinical practice in hospitals with the aim to measure the current level of shared decision-making. Each month from May 2020 onwards, one hospital will make the transition, that will take approximately 1 month, to using shared decision-making supported by outcome data (see the description of the intervention), until all seven hospitals have implemented this in their daily clinical practice. Subsequently, for at least 6 months, we will assess the effectiveness and the extent to which shared decision-making supported by outcome data is implemented. Due to the stepwise design, some hospitals will be monitored longer before the transition, while others will be monitored longer after the transition, allowing us to make between-hospital comparisons. In each hospital 5 patients will be included per month. Patients included before and after the transition will receive a questionnaire and two follow-up questionnaires (after 6 and 12 months) to monitor patients’ experiences in consultation, their daily functioning and other subjects related to the care they received. Also, in each hospital, 15 patients, both before and after the transition, will be asked permission to audio-tape consultations. These will be used to monitor the length of consultation and for two trained observers to assess shared decision-making supported by outcome data during consultation. Healthcare professionals will receive a questionnaire 3 months after the transition phase, to evaluate the effectiveness and extent to which shared decision-making supported by outcome data is implemented.

Intervention

Healthcare professionals, guiding patients facing the decision for follow-up care, will be introduced to a patient decision aid including (personalised) care outcomes, to support the

process of shared decision-making. In addition, they will receive a training on shared decision-making: they will be informed on the guiding principles, motivated to use shared decision-making in clinical practice, and taught how to apply it.

Contacts

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Eligibility criteria

Inclusion criteria

1) Patients must be facing the decision for the organisation of follow-up care after receiving curative treatment for invasive breast cancer (in the first follow-up consultation about 1 year after surgery); 2) Being treated in a Santeon hospital; 3) ≥ 18 years of age; 4) Understand the Dutch language in speech and writing, and; 5) Able to provide informed consent.

Exclusion criteria

1) Patients diagnosed with non-invasive breast cancer (e.g. Ductal Carcinoma In Situ (DCIS)); 2) Patients who receive palliative treatment; 3) Patients who received neoadjuvant therapy; 4) Male breast cancer patients; 5) Patients with dementia; 6) Patients who received treatment for a recurrence or second primary tumor; 7) Patients with a breast cancer-related gene alteration (e.g. BRCA).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2019
Enrollment:	630
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N.A.

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	NL8374
Other	MEC-U; Bureau Onderzoek en Innovatie, Santeon : W19.154 (MEC-U Nieuwegein); 2019-077 (Adviescommissie nWMO Martini Ziekenhuis Groningen)

Study results

Summary results
N.A.