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

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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.

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22492

Bron
Nationaal Trial Register

Verkorte titel
SHOUT-BC

Aandoening

Breast cancer

Ondersteuning

Primaire sponsor: Santeon
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2019
Aantal proefpersonen:	630
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N.A.

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8374
Ander register	MEC-U; Bureau Onderzoek en Innovatie, Santeon : W19.154 (MEC-U Nieuwegein); 2019-077 (Adviescommissie nWMO Martini Ziekenhuis Groningen)

Resultaten

Samenvatting resultaten
N.A.