Decision Aid for Breast Reconstruction after Mastectomy: A Randomized Controlled Trial

No registrations found.

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

Summary

ID

NL-OMON28003

Source
Nationaal Trial Register

Brief title
CARE-trial

Health condition

Breast cancer

Sponsors and support

Primary sponsor: St. Antonius Hospital
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Decisional conflict (measured by the decisional conflict scale [DSC]) directly after the reconstructive decision

Secondary outcome

Immediately after the reconstructive decision:
- Satisfaction with the visit on a 0-10 numerical scale
- Satisfaction with information on a 0-10 numerical scale
- Shared decision making questionnaire (SDM-Q-9) score
- Treatment choice
- Consultation time
- Number of consultations
- Patient-rated physician empathy (measured by CARE)
- Symptoms of depression (measured by PROMIS Short Form Adult V1.0 item bank for depression)
- Symptoms of anxiety (measured by PROMIS Short Form Adult V1.0 item bank for anxiety)

At 12 - 14 months after reconstruction:
- Decision regret (measured by the Decision Regret Scale [DRS])
- Decisional conflict (measured by the Decisional Conflict Scale [DCS])
- Satisfaction with information on a 0-10 numerical scale
- Breast related satisfaction and quality of life (measured by BREAST-Q)
- Subscale Body Image of the EORTC QLQ-BR23
- Subscale Breast Symptoms of the EORTC QLC-BR23
- Symptoms of depression (measured by PROMIS Short Form adult V1.0 item bank for depression)
- Symptoms of anxiety (measured by PROMIS Short Form adult V1.0 item bank for anxiety)
- Changes in treatment choice
- Satisfaction with the treatment on a 0-10 numerical scale
- Change in plastic surgeon

Study description

Background summary

Nowadays, a great variety of techniques for post mastectomy breast reconstruction (PMBR) are available.The considerations regarding PMBR are highly complex.Given the varying risks and benefits of the different types of PMBR, shared decision making (SDM) is important. However, previous literature suggests that patients may feel ill-equipped to participate in SDM due to lack of information or intimidated by the decision process in a phase in which they are confronted with the diagnosis of breast cancer.

Decision Aids (DAs) can assist patients in SDM. Within different disciplines it has been proven that patient DAs to support SDM result in less decisional conflict and more knowledgeable, better informed, less anxious and depressed patients with a better mental well-being. Lastly, we believe DAs may decrease unwanted practice variation in the decisional process.

The aim of this study is to evaluate effects of reviewing a DA (https://www.keuzehulp.info/pp/type-borstreconstructie/intro) for PMBR in the week prior to the first consultation with the plastic surgeon compared to the standard-of-care. The endpoints of this study are: decisional conflict, satisfaction with the visit and information, satisfaction with the treatment, shared decision making, treatment choice, consultation time, number of consultations, physician empathy, breast related satisfaction, symptoms of depression and anxiety, decisional regret, body image, breast symptoms, change in treatment and change in plastic surgeon.

For data collection we will ask consenting subjects to fill out questionnaires at three different moments in time. Filling out these questionnaires will not take longer than 20 - 30 minutes per time-point.

Study objective

In patients considering post mastectomy breast reconstruction there is no difference in decisional conflict (measured by the decisional conflict scale [DSC]) directly after the reconstructive decision between patients receiving standard care and those who review a decision aid prior to the appointment with the plastic surgeon.

Study design

T0: Time of enrollment
T1: Immediately after the reconstructive decision
T2: 12 - 14 months after breast reconstruction

Intervention

We developed a decision aid for breast reconstruction after mastectomy (validated in Dutch): https://www.keuzehulp.info/pp/type-borstreconstructie/intro, utilizing the Ottawa Decision Support Framework. The information is based on current best evidence and updated once every two years or whenever a new guideline is introduced. It takes approximately 15 to 20 minutes to complete the whole decision aid. At the time of enrollment (T0) subjects who are assigned to the intervention group, are asked to complete the decision aid in the week before their first consultation at the plastic surgeon.

Contacts

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Eligibility criteria

Inclusion criteria

- Females.
- Unilateral or bilateral mastectomy.
- Oncologic mastectomy or prophylactic mastectomy.
- Women that quality for a delayed or immediate breast reconstruction.
- Sufficient computer skills.
- Written informed consent.

Exclusion criteria

- Patients < 18 years old.
- History of breast reconstruction.
- Prior visit to discuss breast reconstruction.
- Previous access to an online decision aid per patient report after direct questioning.
- Partial mastectomy or lumpectomy.
- Metastatic disease at presentation.
- Loco regional, distance or contralateral recurrence of illness or death before breast reconstruction.
- Not being able to understand and speak the Dutch language sufficiently.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2020
Enrollment:	120
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	06-08-2019
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	NL7939
Other	MEC-U : W19.176

Study results