The minimal clinically important difference for decisional conflict, impact of event, body image scale and the Short Form-36 among women with breast cancer

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22847

Source
Nationaal Trial Register

Brief title
MINI-CARE

Health condition

Breast cancer

Sponsors and support

Primary sponsor: St. Antonius Ziekenhuis
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

Difference in Decisional conflict scale (DCS) score before and 2 - 4 weeks after surgical decision.

Secondary outcome

- Difference in Impact of event scale (IES) score before and 4 - 6 weeks/6 months after surgical decision.
- Difference in Body Image after Breast Cancer Questionnaire (BIS) before and 4 - 6 weeks/6 months after surgical decision.
- Difference in Short form 36 Health Survey Questionnaire (SF-36) before and 4 - 6 weeks/6 months after surgical decision.

Study description

Background summary

Improved overall survival and heightened awareness combined with increasing attention for prophylactic mastectomies1 are shifting the focus of breast cancer care providers and patients to long term effects of the treatment on health related patient satisfaction and quality of life. Patient reported outcome measurements (PROMs) focus on the patient's perspective and are becoming increasingly important in the evaluation of our treatments. Interpreting changes in scores might however be challenging as a significant difference does not equal a clinically relevant difference.

The minimal clinically important difference (MCID) is the smallest change in treatment outcome score that a patient, a care provider, or both would perceive as important. Treatments showing a statistically significant difference in scores that are lower than the MCID may not be actually clinically relevant. Therefore, establishing the MCID for outcome measures is essential to determine treatment effectiveness and therefore in sample size calculation in trial design.

At present, there is no standard as to how to assess the MCID. Different methods exist to determine the MCID: (1) based on the data's distribution, (2) by a Delphi (expert-based) approach7 or (3) through an anchor-question. Generally, the anchor-based approach is accepted as the preferred method as it takes into account both statistical distribution and patient perspectives.

The MCID probably varies by diagnosis, treatment and in time. At present, the MCID for commonly used PROMs in breast cancer (DCS, IES, BIS and SF-36) is unknown.

In this study we aim to determine the MCID for DCS in women with breast cancer 2-4 weeks after visiting our outpatient breast cancer center using an anchor question and the MDIC 4-6 weeks postoperative and 6 months postoperative for IES, BIS and SF-36. Secondarily, we will assess flooring and ceiling effects and factors associated with low scores for DCS, IES, BIS

and SF-36 among this population. We hypothesize that there are no factors associated with achieving an MCID for DCS, IES, BIS and SF-36.

Study objective

We hypothesize that there are no factors associated with achieving an MCID for DCS, IES, BIS and SF-36.

Study design

- 2 - 4 weeks after surgical decision.
- 4 - 6 weeks after surgical decision.
- 6 months after surgical decision.

Intervention

Consenting subjects are invited to fill out a panel of standardized questionnaires, including the DCS, IES, BIS, SF-36, PROMIS Short Form Anxiety and Depression, PCS, GSE (self-efficacy), and a study specific questionnaire.

Contacts

Public
St. Antonius Nieuwegein
Claudia Bargon

0031653952756
Scientific
St. Antonius Nieuwegein
Claudia Bargon

0031653952756

Eligibility criteria

Inclusion criteria

- Women with the diagnosis of in situ or invasive breast cancer visiting the outpatient clinic of the oncological surgery department in the St. Antonius Hospital.
- Indication for surgical treatment.

- Written informed consent.

Exclusion criteria

- History of breast cancer.
- No indication for surgery.
- Age < 18 years old.
- Not being able to understand and speak the Dutch language sufficiently.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-02-2020
Enrollment:	120
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	25-02-2020
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	NL8410
Other	MEC-U : W19.210

Study results