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

Gepubliceerd: 25-02-2020 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22847

Bron
Nationaal Trial Register

Verkorte titel
MINI-CARE

Aandoening

Breast cancer

Ondersteuning

Primaire sponsor: St. Antonius Ziekenhuis
Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	25-02-2020
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	25-02-2020
Soort:	Eerste indiening

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	NL8410
Ander register	MEC-U : W19.210

Resultaten