

Genetic testing in breast cancer patients based on a home information package: DNA-direct.

Gepubliceerd: 10-08-2011 Laatste bijgewerkt: 15-05-2024

This study will offer breast cancer patients who are referred for genetic testing, the option of replacing initial face-to-face genetic counseling prior to DNA-testing (DNA-intake procedure) by an information package of telephone, written and...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22096

Bron

Nationaal Trial Register

Verkorte titel

DNA-direct

Aandoening

BRCA1/2, breast cancer, borstkanker, hereditary breast cancer, erfelijke borstkanker

Ondersteuning

Primaire sponsor: UMC St Radboud / Radboud University Medical Center (Nijmegen)

Overige ondersteuning: Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Satisfaction of the patient (i.e. RIVM-questionnaire, Decisional Conflict Scale, open-ended questions);

2. Psychological / psychosocial burden of the patient (i.e. Impact of Event Scale, questions regarding quality of life (selected from EORTC-QLQ C30), GHQ-12, Cancer Worry Scale, risk perception of hereditary and recurrent breast cancer on a scale of 0-100%).

Toelichting onderzoek

Achtergrond van het onderzoek

The aim of this study is to evaluate the effects of replacing face-to-face genetic counseling prior to genetic testing (DNA-intake procedure) by a home information package (DNA-direct procedure), on the satisfaction and psychological/psychosocial burden of breast cancer patients, as well as the speed and quality of genetic advice. 150 patients who are or have been in treatment for breast cancer and are referred to the department of Clinical Genetics of the Radboud University Medical Centre (Nijmegen, the Netherlands) for genetic counseling, may choose between the DNA-intake or DNA-direct procedures, prior to DNA-testing. All patients included should not have problems with Dutch text or with family communication, nor be in treatment for psychological/psychiatric diseases. All patients receive the same two questionnaires when included (baseline) and after completion of genetic counseling (follow-up). A small selection of patients is also invited for a semistructured interview by telephone. By offering the DNA-direct procedure, we hope to optimize genetic counseling for patients with breast cancer: information customized to DNA results, shortening the period of uncertainty and the possibility of taking genetic advice into account for the treatment and follow-up of breast cancer.

Doel van het onderzoek

This study will offer breast cancer patients who are referred for genetic testing, the option of replacing initial face-to-face genetic counseling prior to DNA-testing (DNA-intake procedure) by an information package of telephone, written and digital information sent to their homes (DNA-direct procedure). We want to evaluate the effects of the DNA-direct procedure on the experience and psychosocial burden of breast cancer patients, as well as the speed and quality of genetic advice, as compared to the current DNA-intake procedure. We hypothesize that undergoing the DNA-direct procedure does not lead to increased levels of psychosocial burden as compared to the current DNA-intake procedure, showing equal levels of patient satisfaction plus shorter waiting and processing times. Thus, we expect DNA-direct to be an acceptable procedure for breast cancer patients to undergo genetic testing, leading to more customized care.

Onderzoeksopzet

At inclusion (T0), baseline questionnaire:

1. General demographic information;
2. Psychological / psychosocial burden;
3. Empowerment.

After completion of genetic counseling (T1, at least 8 weeks after baseline), follow-up questionnaire:

1. Psychological / psychosocial burden;
2. Reasons for choosing for or against the DNA-direct procedure;
3. Satisfaction with genetic counseling and testing;
4. Personal experiences and satisfaction with chosen procedure;
5. Family relations and communication about cancer.

After completion of the follow-up questionnaire (T3), a small selection of patients receive an invitation for a 30 minute semistructured interview by telephone. Patients are selected for an interview if they are confirmed carriers of a BRCA1/2 mutation, if they report problems with the chosen procedure, or randomly (n=10).

Onderzoeksproduct en/of interventie

DNA-direct procedure:

Replacing the current initial face-to-face consultation to provide general information about hereditary breast cancer and genetic testing (DNA-intake procedure), by a home information package of telephone, written and digital information (website and specially made educational movie). DNA-testing will be performed prior to face-to-face genetic counseling, contrary to the current practice (DNA-intake), where genetic counseling precedes DNA-testing. Disclosure of DNA-results will always follow in a face-to-face consultation in both DNA-direct and DNA-intake procedures.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All female breast cancer patients (recently diagnosed or in the past) referred to the department of Clinical Genetics of the Radboud University Medical Centre Nijmegen for genetic counseling.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Problems with (large amounts of) written Dutch text;
2. Current psychological / psychiatric treatment (including medication);
3. Problems with family communication about cancer as estimated by the patient.

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	08-08-2011
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	10-08-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 35994
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2873
NTR-old	NTR3018
CCMO	NL36219.091.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35994

Resultaten

Samenvatting resultaten

N/A