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

No registrations found.

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

Summary

ID

NL-OMON22096

Source
NTR

Brief title
DNA-direct

Health condition

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

Sponsors and support

Primary sponsor: UMC St Radboud / Radboud University Medical Center (Nijmegen)
Source(s) of monetary or material Support: Sponsor

Intervention

Outcome measures

Primary outcome

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%).

Secondary outcome

1. Factors that determine the patient's choice for or against the DNA-direct procedure (i.e. demographic information, Empowerment (NEV-bk), open-ended questions);

2. Waiting and processing times;

3. Family characteristics of detected families with a mutation in the BRCA1 or BRCA2 gene (i.e. ODHCF).

Study description

Background summary

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 optimalize 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.

Study objective

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.

Study design

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).

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-08-2011
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-08-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35994
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results
N/A