Communicating breast cancer risks: a genetic counsellor's role in improving patient understanding to increase informed decisionmaking

Submission date Recruitment status Prospectively registered 12/09/2005 No longer recruiting [X] Protocol [] Statistical analysis plan Registration date Overall study status 12/09/2005 Completed [X] Results [] Individual participant data Last Edited Condition category 07/05/2013 Cancer

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

KWF number: VU 2004-2994; NTR89

Study information

Scientific Title

Acronym

BRISC

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised, active controlled, parallel group, double-blinded trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Mammary carcinoma

Interventions

The intervention-additional risk information is given to healthy women with a family history of breast cancer immediately after standard counselling with the clinical geneticist. The intervention consists of one of five conditions that differ in the way risk is communicated, that is:

- 1. Life-time breast cancer risk in a numerical format
- 2. Life-time breast cancer risk in a numerical and graphical format
- 3. Both life-time risk and age-related breast cancer risk in a numerical format
- 4. Both life-time risk and age-related breast cancer risk in a numerical and graphical format
- 5. Control group

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Adequate risk perception

Key secondary outcome(s))

- 1. Cognitive evaluation (knowledge about hereditary breast cancer, informed decisions)
- 2. Psychological and affective evaluation ([cancer] anxiety, worry)
- 3. Evaluation of perceived benefits and helpfulness of the additional risk counselling
- 4. Expected intention or actual uptake of methods of breast cancer detection and prevention

Completion date

15/07/2008

Eligibility

Key inclusion criteria

A consecutive series of women who are first time attenders applying for genetic breast cancer counselling at three Dutch Clinical Genetic Centres (VUmc Amsterdam, LUMC Leiden and UMCG Groningen) are invited to participate in the study.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Women are considered ineligible if they are:

- 1. Less than 18 years of age
- 2. Have evident psychiatric illness
- 3. Have a terminal disease
- 4. Women with a personal history of breast or ovarian cancer

Date of first enrolment

15/07/2004

Date of final enrolment

15/07/2008

Locations

Countries of recruitment

Netherlands

Study participating centre VU Medisch Centrum

Amsterdam Netherlands 1081 B

Sponsor information

Organisation

VU University Medical Centre/EMGO-Institute (The Netherlands)

ROR

https://ror.org/00q6h8f30

Funder(s)

Funder type

Charity

Funder Name

Dutch Cancer Society (KWF Kankerbestrijding) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/04/2013		Yes	No
<u>Protocol article</u>	study protocol	03/10/2008		Yes	No