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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

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 measure
Adequate risk perception

Secondary outcome measures
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

Overall study start date
15/07/2004

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

Age group
Adult

Sex
Female

Target number of participants
300

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)

Sponsor details
Van der Boechorststraat 7
Amsterdam
Netherlands
1081 BT
+31 (0)20 444 8180
emgo@vumc.nl

Sponsor type
Hospital/treatment centre

Website
http://www.vumc.nl/

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Charity

Funder Name
Dutch Cancer Society (KWF Kankerbestrijding) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	study protocol	03/10/2008		Yes	No
Results article	results	29/04/2013		Yes	No