

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

<b>Submission date</b> 12/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/05/2013	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr D R M Timmermans

### Contact details

VU Medisch Centrum  
Afd Sociale Geneeskunde  
Van der Boechorststraat 7  
Amsterdam  
Netherlands  
1081 B

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# 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?
<a href="#">Protocol article</a>	study protocol	03/10/2008		Yes	No
<a href="#">Results article</a>	results	29/04/2013		Yes	No