Longterm psychological riskprofiles in women at risk for hereditary breast cancer adhering to surveillance or opting for prophylactic mastectomy

Published: 18-12-2006
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To identify the determinants of psychological vulnerability through time (for the development of the prognostic risk profiles)

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive tract and breast disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON30298

Source
ToetsingOnline

Brief title
psychological risk profiles in women at risk for hereditary breast cancer

Condition

- Reproductive tract and breast disorders congenital
- Breast disorders

Synonym
increased risk for hereditary breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Koningin Wilhelmina Fonds

Intervention

Keyword: BRCA1/2, breast cancer, coping, psychological distress

Outcome measures

Primary outcome

The outcome variables are psychological variables regarding distress (anxiety, depression and breast cancer specific distress). The primary aim of the study is to identify risk profiles for distress in the long term. The following variables are of importance: coping, risk perception, family history of (breast) cancer, communication style within the family and self-efficacy.

Secondary outcome

not applicable

Study description

Background summary

The current study is a follow-up study on two earlier projects about the psychological consequences of regular surveillance on the one hand and prophylactic surgery on the other in women at increased risk of developing breast cancer due to an identified hereditary predisposition or family history. In general both groups of women psychologically seem to function well. However, in both earlier projects several subgroups of women who were more vulnerable for heightened psychological distress were found. It is warranted to identify these women as early as possible. To examine this both groups of women will be asked to participate in this follow-up study in order to identify short- and long-term risk profiles for women who experience heightened psychological distress

Study objective

To identify the determinants of psychological vulnerability through time (for

the development of the prognostic risk profiles)

Study design

Both groups of women (EMC-DDHK 98-22B, MRISC studie; EMC-DDHK 98-15B, PREVOM studie) will be asked to participate in this follow-up study. The surveillance group will fill in questionnaires around two consecutive surveillance appointments in the clinic. The prophylactic surgery group will fill in questionnaires around their annual surveillance appointment. A randomly selected subgroup of women will receive an interview on the baseline measurement moment.

Study burden and risks

The burden put on the participants will be minimal. A questionnaire is to be filled in five times. The first questionnaire will take 45 minutes maximum to fill in, the other questionnaires 15 minutes. All participants will be familiar with this procedure and the nature of most of the questions. The interview which will be conducted in a randomly selected subgroup will take 60 minutes maximum and will be held at the participants home. There are no risks associated with participation in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

increased risk for hereditary breast cancer
adhering to regular surveillance or having had a prophylactic mastectomy
understand spoken and written Dutch

Exclusion criteria

current breast cancer diagnosis

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2007
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	18-12-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL14463.078.06