Behavioral and psychosocial effects of rapid genetic counseling and testing in newly diagnosed breast cancer patients: a multicenter study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Congenital and hereditary disorders NEC
Study type	Interventional

Summary

ID

NL-OMON32529

Source
ToetsingOnline

Brief title
TIME-trial

Condition

- Congenital and hereditary disorders NEC
- Breast neoplasms malignant and unspecified (incl nipple)
- Breast therapeutic procedures

Synonym
breast cancer, breast neoplasm

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: Stichting NutsOhra

Intervention

Keyword: breast cancer, genetic counseling

Outcome measures

Primary outcome

Standardized questionnaires will be administered to all patients at study entry, and at 6 and 12 months to assess all psychosocial outcomes. The study endpoints will include: (1) the choice of clinical management strategy, including the uptake of direct bilateral mastectomy (BLM) or of delayed preventive contralateral mastectomy (PCM); (2) cancer risk perception, cancer-related worry and distress; (3) knowledge of genetic aspects of breast cancer; (4) decisional satisfaction; and (5) health-related quality of life (HRQL).The study will also evaluate women*s experience of and satisfaction with RGCT (i.e., the timing and quality of the services provided, the perceived impact on treatment decisions, perceived need for additional psychosocial services, etc.). Data on surgical outcomes will be abstracted from the medical records. A subset of women will be interviewed to obtain supplementary, qualitative data about the RGCT experience.

Secondary outcome

See primary study parameters

Study description

Background summary

In the Netherlands, breast cancer is the most common form of cancer. Approximately 12,000 women are diagnosed annually, of whom about 5-10% carry a mutation in a breast cancer gene. Genetic counseling and DNA testing are usually offered to selected patients after primary treatment has been completed (e.g. the first year after diagnosis). For women with a mutation in one of the two breast-ovarian cancer syndrome genes, BRCA1 and BRCA2, chances of a second breast cancer are high, and therefore a proportion of these women may opt for preventive measures in addition to their immediate breast cancer treatment. Contralateral prophylactic mastectomy significantly reduces this risk, and is associated with a reduction in mortality. Genetic counseling and testing for breast cancer typically takes approximately 4-6 months to complete. However, some hospitals and laboratories are now able to generate test results within 3 to 6 weeks. This technology of rapid genetic testing creates new opportunities for providing both women and their treating surgeons with information potentially relevant for deciding between available treatment options, including type of surgery and adjuvant therapy. It is expected that women with a BRCA gene mutation more often will opt for a bilateral mastectomy. However, research is needed to determine if this hypothesis is correct. Additionally, few data are as yet available on the treatment-related and psychosocial consequences of genetic testing and risk-reducing behavior among individuals with a recent diagnosis of breast cancer.

Study objective

The proposed study will focus on newly diagnosed breast cancer patients who, prior to receiving treatment, are identified on the basis of age or family history of breast or ovarian cancer as having at least a 10% risk of carrying a mutation in the BRCA1 or BRCA2 genes. We will investigate whether women with a recent diagnosis of breast cancer make use of rapid genetic counseling when offered. Furthermore, we will investigate whether the process of genetic counseling (and subsequent DNA testing) has influence on the choice of treatment, and whether and how such rapid genetic counseling and testing (RGCT) affects levels of risk perception, cancer-related worries and distress, and decisional satisfaction.

Study design

This multicenter study will employ a randomized controlled trial. In an 18 month period newly diagnosed breast cancer patients will be recruited from 13 hospitals in the Amsterdam and Utrecht regions of the Netherlands. Eligible patients will be randomized either to the *usual care* (UC) arm of the study,

or to the RGCT arm of the study. The randomization will be done in a ratio of 1:2, leading to 85 patients in the UC arm and 170 patients in the RGCT arm.

Women in the RGCT arm of the study will be referred for genetic counseling within a week after diagnosis, prior to the primary surgery. Genetic counseling will take place at the NKI-AVL or the UMC Utrecht, If a DNA-test is indicated, a blood sample for this test can be provided by the patient on the same day. If necessary, the results will be known within 3 to 6 weeks.

Women in the UC condition will receive standard advice and care from their treating physician. In some cases, patients may be referred by the treating surgeon or self-refer to genetic counseling. However, in current practice, this occurs rarely during the pre-surgery period.

Standardized questionnaires will be administered to all patients at study entry, and at 6 and 12 months to assess all psychosocial outcomes. The study endpoints will include: (1) the choice of clinical management strategy, including the uptake of direct bilateral mastectomy (BLM) or of delayed preventive contralateral mastectomy (PCM); (2) cancer risk perception, cancer-related worry and distress; (3) knowledge of genetic aspects of breast cancer; (4) decisional satisfaction; and (5) health-related quality of life (HRQL).The study will also evaluate women*s experience of and satisfaction with RGCT (i.e., the timing and quality of the services provided, the perceived impact on treatment decisions, perceived need for additional psychosocial services, etc.). Data on surgical outcomes will be abstracted from the medical records. A subset of women will be interviewed to obtain supplementary, qualitative data about the RGCT experience.

During 18 months about 2550 women in the regions of Amsterdam and Utrecht will be diagnosed with breast cancer. Based on previous research, the estimated number of women with a probable hereditary form of breast cancer is 400. We expect that 255 of these women will participate in the study.

Intervention

Women in the RGCT arm of the study will be referred for genetic counseling within a week after diagnosis, prior to the primary surgery. Genetic counseling will take place at the NKI-AVL or the UMC Utrecht, If a DNA-test is indicated, a blood sample for this test can be provided by the patient on the same day. If necessary, the results will be known within 3 to 6 weeks.

Study burden and risks

Answering the questionnaires will take about 45-60 minutes each time.
For some people answering questions about their health and cancer risks, might be a burden.

The information given during genetic counseling might be a burden.

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

women with breast cancer, with an indication for genetic counseling and dna-testing.

Exclusion criteria

Age < 18 years
Non-Dutch speakers

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2008
Enrollment:	255
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL24254.031.08