Patient empowerment by group medical consultations in the follow-up of breast cancer survivors and surveillance of women with a BRCA mutation

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A) Follow-up of breast cancer patientsPrimary research question1.In the follow-up of breast cancer patients: does a group medical consultation (GMC) increase patient empowerment compared to a regular individual visit and/or does it decrease...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON34236

Source
ToetsingOnline

Brief title
GMC trial

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Ministerie van OC&W,Stichting Pink Ribbon

Intervention

Keyword: BRCA mutation, breast cancer, group medical consultation

Outcome measures

Primary outcome

n.a.

Secondary outcome

n.a.

Study description

Background summary

A group medical consultation (GMC), or shared medical appointment, is an innovative way of consultation. During a GMC the healthcare worker provides a series of one-to-one consultations in a group of ~10 patients; the group is facilitated by a behavioral health professional. These group appointments provide patients with the opportunity to spend extended time with their care providers, while sharing in an interactive setting and learning from other patients. This may improve patient care compared to an individual consultation. However, group sessions may also work out negatively and increase patient distress. Therefore, before introducing GMCs in regular patient care the value of GMCs for specific patient populations should carefully be evaluated. In this research project we will evaluate the value of GMCs in the follow-up of breast cancer survivors and the surveillance of women with a BRCA mutation.

Study objective

A) Follow-up of breast cancer patients
Primary research question
1.In the follow-up of breast cancer patients: does a group medical consultation (GMC) increase patient empowerment compared to a regular individual visit and/or does it decrease psychological distress?

Secondary research questions
1.In the follow-up of breast cancer patients does a GMC compared to a regular individual visit:

a) decrease fear of breast cancer?
b) improve transfer of information?
c) improve adherence to hormonal treatment?
d) improve patient satisfaction?
e) improve caregiver satisfaction?

2.In the follow-up of breast cancer patients is a GMC cost effective compared to a regular individual visit?

B) Surveillance of BRCA mutation carriers
Primary research question
1.In the surveillance of women with a BRCA mutation: does a group medical consultation (GMC) increase patient empowerment compared to a regular individual visit and/or does it decrease psychological distress?

Secondary research questions
1.In the surveillance of women with a BRCA mutation does a GMC compared to a regular individual visit:
a) decrease fear of breast cancer?
b) improve transfer of information?
c) improve adherence to self-control of the breasts?
d) change the decision for a prophylactic mastectomy or surveillance?
e) improve patient satisfaction?
f) improve caregiver satisfaction?

2.In the surveillance of women with a BRCA mutation is a GMC cost effective compared to a regular individual visit?

Study design

Two separate randomized controlled trials will be performed for patients in follow-up after breast cancer and women with a BRCA mutation. In the experimental group women will participate in a GMC instead of a regular individual visit; in the control group women will have their regular individual visit.

Intervention

GMC versus regular individual consultation

Study burden and risks

n.a.

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

Participants: patients in follow-up after breast cancer
Women >= 18 years of age with histologically proven breast cancer.
Primary treatment (surgery, radiotherapy, chemotherapy) completed maximally 5 years ago.
;Participants: women with a BRCA mutation
Women >= 25 years of age with a proven BRCA1 or BRCA2 mutation.
Carrier of a BRCA1 or BRCA2 mutation, diagnosed maximally two years before inclusion.

Exclusion criteria

Participants: patients in follow-up after breast cancer
Currently involved in a diagnostic work-up because of a suspicion of breast cancer, either

primary or metastatic.
A history of prophylactic mastectomy.
Current psychiatric disease precluding consultations in a group.
Insufficient command of the Dutch language to be able to follow a group discussion and/or to fill out a Dutch questionnaire. ;Participants: women with a BRCA mutation
Currently involved in a diagnostic work-up because of a suspicion of breast cancer, either primary or metastatic.
A history of prophylactic mastectomy.
Current psychiatric disease precluding consultations in a group.
Insufficient command of the Dutch language to be able to follow a group discussion and/or to fill out a Dutch questionnaire.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-04-2011
Enrollment:	344
Type:	Actual

Ethics review

Approved WMO

Date:	27-01-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	17-11-2011
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-03-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-02-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23985
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL34511.091.10
OMON	NL-OMON23985

Study results

Date completed:	11-09-2014
Actual enrolment:	325