Familieleden informeren over de kans op kanker en preventieve maatregelen.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25373

Source
Nationaal Trial Register

Health condition

Hereditary breast cancer
Hereditary colon cancer
Family communication
Genetic counseling
Relatives
Risk communication

Erfelijke borstkanker
Erfelijke darmkanker
Familiecommunicatie
Genetische counseling
Familieleden informeren
Risicocommunicatie

Sponsors and support

Primary sponsor: Academic Medical Centre
Source(s) of monetary or material Support: KWF cancer society

Intervention

Outcome measures

Primary outcome

1. Knowledge, which comprises:

A. Insight into which relatives need to be informed;

B. Risk perception;

C. General knowledge about hereditary cancer;
br>
D. Knowledge about surveillance measures for relatives.

2. Motivation;

3. Self-efficacy.

Secondary outcome

1. Number of informed relatives;

2. Knowledge in relatives;

3. Relatives' intention to engage in genetic counseling, testing and/or preventive screening.

Question 2a: Does our intervention lead to counselees informing more relatives?
This question will be answered by asking counselees at the four months follow-up (T3) to indicate the number of relatives they informed.

Question 2b: Does our intervention lead to increased knowledge in relatives about hereditary or familial cancer and preventive measures?
Relatives’ knowledge will be assessed using the same instrument as for counselees, comprising their insight into which relatives need to be informed, risk perception and general knowledge about hereditary breast cancer or colon cancer including knowledge about preventive measures.

Question 2c: Does our intervention increase informed relatives’ intention to engage in genetic counseling, testing and/or preventive screening?
Intentions will be measured using the following format 'How likely is it that you will have a

colonoscopy in the next year?'. Items will be scored as 1 = very unlikely, to 5 = very likely.

Question 3: Which sociodemographic, personal, familial and clinical characteristics of counselees are associated with a) knowledge, motivation and self-efficacy with regard to disclosing information about cancer risk and preventive measures to at risk relatives and b) with the number of informed relatives? To answer these questions, the following counselee characteristics will be assessed at (T1).

Study description

Background summary

Purpose:

The identification of a hereditary or familial breast or colon cancer risk has not only implications for the counselee, but also for his or her relatives. Relatives may need to be informed about their possible risk. Based on this risk information, they can make an informed decision about whether or not to pursue genetic counseling, testing and/or preventive breast or colon screening. Genetic counselors therefore encourage counselees to discuss cancer risks and preventive measures with their relatives. However, fewer relatives present to genetic services for care than would be expected. Of at risk first degree relatives, an average of 40% present to genetic services for care. Percentages for 2nd and 3rd degree relatives are lower. The limited uptake of genetic and surveillance services raises the question whether and how at risk relatives are informed by the counselee. Literature suggests that counselees may encounter barriers in family disclosure that result from 1) lack of knowledge (e.g., not knowing who is at risk), 2) lack of motivation to inform (e.g., wanting to protect relatives for negative emotions) and 3) lack of self-efficacy, i.e., not being able to inform (e.g., loss of contact).

We aim to develop and evaluate an intervention focused at supporting counselees in disclosing information about cancer risks and preventive measures to their relatives.

Our primary research question is:

1. Does such an intervention increase counselees’ knowledge, motivation and self-efficacy with regard to disclosing information about cancer risks and preventive measures to at risk relatives?

Secondary questions are:

2. Does such an intervention:

A. Lead to counselees informing more relatives?

B. Lead to increased knowledge in relatives about hereditary or familial cancer and preventive measures?

C. Increase informed relatives' intention to engage in genetic counseling, testing and/or preventive screening?

3. Which sociodemographic, personal, familial and clinical characteristics of counselees are associated:

A. With knowledge, motivation and self-efficacy regarding the disclosure of information about cancer risk and preventive measures to at risk relatives?

B. With the number of informed relatives?

Plan of investigation:

Counselees in the control group (n=132) will receive standard care. Counselees in the intervention group (n=132) will receive additional counseling by telephone, provided by one of five psycho-social workers, aimed at whether and how best to inform at risk relatives. This intervention will be based on the principles of Motivational Interviewing. Assessments, using questionnaires, will take place after the final regular genetic counseling session (T1), immediately following the intervention (T2) and at 4 months after the intervention (T3). At T2, a part of the questionnaire will be completed together with the researcher by phone. The primary outcomes of the study comprise the counselees' knowledge, motivation and self-efficacy regarding the dissemination of information about cancer risk information and preventive measures into the family.

Relevance:

Genetic counselors rely on counselees to inform their relatives about their hereditary or familial cancer risk and possibilities to reduce this risk. It is therefore essential that their ability to be a competent, motivated and confident informant is maximized, while respecting their wish not to inform (some) relatives. The proposed intervention will 1) support counselees in this difficult task and 2) hopefully allow more at risk relatives to make a well informed decision. This may lead to more relatives taking up genetic services and preventive screening, if needed. Consequently cancer morbidity and mortality will be reduced in affected families.

Study objective

We aim to develop and evaluate an intervention focused at supporting counselees in disclosing information about cancer risks and preventive measures to their relatives.

We assume that the intervention will increase counselees' knowledge, motivation and self-efficacy with regard to disclosing hereditary cancer information to at risk relatives.

Study design

T1: Before the intervention (when counselees have received the summary letter fromt he Clinical Genetics department);

T2: After the intervention (and 4 weeks after T1 for the control group;

T3: 4 months after the intervention.

Intervention

The intervention consists of an additional counseling session by telephone based on the principles of Motivational Interviewing and performed by psychosocial workers.

The control group will receive care as usual.

Contacts

Public
Academic Medical Centre
Department of Medical Psychologie
Meibergdreef 15
E. Geus, de
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5667787
Scientific
Academic Medical Centre
Department of Medical Psychologie
Meibergdreef 15
E. Geus, de
Amsterdam 1105 AZ

The Netherlands
+31 (0)20 5667787

Eligibility criteria

Inclusion criteria

1. Index-patient (first in the family to visit the department of Clinical Genetics for hereditary or familial colon or breast cancer);

2. At least one relative at risk for breast or colon cancer, i.e. eligible for genetic counseling and/or surveillance;

3. Aged 18 years and over;

4. Able to read and write Dutch;

5. Informed consent.

Exclusion criteria

1. Mentally impaired;

2. Unable to independently complete a questionnaire;

3. Not literate in Dutch.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2012
Enrollment:	264
Type:	Actual

Ethics review

Positive opinion

Date:	10-12-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39133
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3594
NTR-old	NTR3745
CCMO	NL40153.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39133

Study results

Summary results
N/A