Informing relatives about their cancer risk and preventive measures. A trial to assess the effectiveness of additional counseling.

Published: 02-08-2012
Last updated: 19-03-2025

The aim of this study is to evaluate an intervention aimed at improving family disclosure of inherited cancer risks by 1) supporting counselees in what they experience as a necessary, but at times difficult, task and, consequently 2) provide more at...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Interventional

Summary

ID

NL-OMON39133

Source
ToetsingOnline

Brief title
Informing relatives about their cancer risk and preventive measures.

Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Malignant and unspecified neoplasms gastrointestinal NEC
- Breast disorders

Synonym
hereditary or familial breast cancer, hereditary or familial colon cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Koningin Wilhelmina Fonds

Intervention

Keyword: family communication, genetic counselling, hereditary breast cancer, hereditary colon cancer

Outcome measures

Primary outcome

The primary outcome constitutes the degree of knowledge, motivation and

self-efficay of counselees with regard to disclosing cancer risks and

preventive measures to relatives.

Secondary outcome

secondary outcomes include:

- the number and proportion of relatives informed by counselees

- relatives' knowledge about hereditary cancer and preventive measures

- relatives' intention to engage in genetic counseling

Study description

Background summary

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 need to be informed about their possible risk so they can make an informed decision about whether or not to pursue genetic counseling, testing and/or preventive breast or colon screening. Generally, fewer relatives present to genetic services for care than would be expected. Of first degree relatives, an average of 40% present to genetic services for care. Percentages for 2nd and 3rd degree relatives are even lower. The limited uptake of genetic and screening 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 which result from lack of knowledge (e.g. not knowing who is at risk), not being motivated to inform (e.g. wanting to protect relatives for negative emotions) and not being able to inform (e.g. loss of contact).

Study objective

The aim of this study is to evaluate an intervention aimed at improving family disclosure of inherited cancer risks by 1) supporting counselees in what they experience as a necessary, but at times difficult, task and, consequently 2) provide more at risk relatives with the opportunity to make an autonomous, well informed decision (not) to go for genetic counseling, testing and/or preventive screening

More specifically, we will aim to answer the following research questions:
Does one additional counselling session, focused at counselees* disclosure of genetic risk and preventive measures for cancer to relatives lead to
1. counselees feeling more knowledgeable, motivated and capable to disclose genetic risk information to their at risk relatives, and
2. counselees informing more at risk relatives,
3. increased knowledge about hereditary cancer and preventive measures in relatives,
4. increased intention among relatives to engage in genetic counseling, testing and/or preventive screening?

Study design

To this end we propose a randomized clinical trial. Counselees in the control group (n= 132) will receive standard care. Counselees in the intervention group (n=132) will receive one additional counseling session, 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, consisting of questionnaires, will take place before the final scheduled regular genetic counseling session (T1), immediately following the intervention (T2) and at 4 months after the intervention (T3). A part of the questionnaire at T2 will be completed together with the researcher by telephone.
At the final assessment counselees are asked if they are willing to ask relatives with whom they shared the hereditary risk information to participate in the study. These relatives will receive one questionnaire.

Intervention

(Index) patients in the intervention group will receive an additional counseling session aimed at informing at risk relatives. This session will be delivered by a psycho-social worker and will take place two weeks after they

received the summary letter from the department of Clinical Genetics. This will allow counselees some time to reflect on the implications of the (test) result for themselves and their relatives, and to anticipate possible obstacles in informing at risk relatives. The intervention will be delivered by telephone.

Study burden and risks

The burden of the study will comprise the completion of three questionnaires by all participating counselees. Completion in total will take 60 minutes. Counselees in the intervention group will additionally receive a telephone counselling session delivered by a psychosocial worker. This session will last on average 30 minutes. Relatives complete one questionnaire.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1100 DD
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1100 DD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion criteria for counselees:
1) index-patient (the first in their family to visit the department of Clinical Genetics for hereditary or familial colon or breast cancer),
2) at least one relative at increased 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 and
5) informed consent. ;Inclusion criteria for relatives:
1) permission of the counselee,
2) aged 18 years and over,
3) able to read and write Dutch and
4) informed consent.

Exclusion criteria

1) mentally impaired
2) unable to independently complete a questionnaire
3) they are not literate in Dutch

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2012
Enrollment:	1200
Type:	Actual

Ethics review

Approved WMO Date:	02-08-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-07-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 25373
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	3745
CCMO	NL40153.018.12
OMON	NL-OMON25373