Web-based tailored information and question prompt for enhancing counselee participation and outcome; a RCT in breast cancer genetic counselling

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

Summary

ID

NL-OMON30644

Source
ToetsingOnline

Brief title
Rct in breast cancer genetic counselling

Condition

- Chromosomal abnormalities, gene alterations and gene variants

Synonym
genetic counseling, Hereditary breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: KWF Kankerbestrijding;sophialaan 8;1075 BR Amsterdam. tel 020 5700520 (project NIVEL 2006-3469)

Intervention

Keyword: Breast cancer, Communication, Genetic counselling, Web-based tailored info

Outcome measures

Primary outcome

Primary outcome measures are counselees' participation, i.e. content and amount

of questions asked and information received during the visit.

Secondary outcome

Additionally the following variables are measured:

- expectations of genetic counselling

- information recall

- need fulfillment

- satisfaction

- pre-post changes in breast cancer knowledge

- risk perception

- perceived personal control

- cancer worry

- anxiety

- optimism

- ilness perception

- (intended) adherence to screening advices or prophylactic surgery at 12

months

- satisfaction with E-info gene

- satisfaction with the genetic counselling

Study description

Background summary

In 2003 over 35% of counselees at Dutch clinical genetic centers were referred because of cancer, 90% of which concerns breast cancer. At least 5% of all breast cancer is considered hereditary. The goal of counselling is to personalize technical and probabilistic genetic information to enable well-informed decisions. Yet, our previous study in 130 initial cancer genetic counselling visits showed that the information provided is relatively standard. More tailored and psychosocially oriented information is not given routinely unless counselees request it specifically. Our study also showed that many counselees are dissatisfied with the way emotional matters are discussed and that dissatisfaction leads to experiencing less personal control and more anxiety. This may influence adherence to screening advices negatively. As many counselees do not know what to expect from genetic counselling, they may be unable to formulate specific questions and needs on medical, psychosocial and emotional issues. To improve outcome, counselees should be specifically prepared and encouraged to formulate and disclose questions and concerns. For this purpose, a preparatory web-based intervention for increasing counselee question asking and participation might be feasible, attractive and easy to implement. The web-based information will include different levels of up-to-date genetic and psychosocial information which can be viewed as needed, and a question prompt sheet. Analysis of counselees' searching behaviour (page-views, time online) will reveal what information is retrieved and favoured most. To increase the impact of the intervention, counsellors are instructed to review the prompted questions before the visit.

Study objective

This study aims to establish the effectiveness of web-based counselee-tailored information plus question prompt designed to 1) increase realistic expectations of breast cancer genetic counselling, 2) facilitate participation, question asking and information exchange, 3) improve outcome by decreasing cancer worry and anxiety and increasing knowledge, correct risk perception, personal control, optimism and correct illness peception and 4) improve adherence to advices.

Study design

Using a randomised controlled trial, this study examines the effectiveness of an innovative web-based intervention on counselling process and outcome. 200 counselees referred for breast cancer to the Department of Medical Genetics of University Medical Center Uterecht and having internet acces at home will be included. Counselees will be randomly assigned to receive only standard information (currently distributed leaflet) or to additionally receive web-based tailored information including question prompt and counsellor review (E-info gene ca). All information is given at least 72 hours before the initial visit.

At least three questionnaires will be sent to the counselee. One before the initial visit, one after the initial visit and repeat visits, if any, and the last 12 months after the last genetic counseling visit. These questionaires measure breastcancer knowledge, risk perception, cancer worry and locus of control. Additionally the first questionnaire asks for expectations of the initial visit and the last two questionnaires measure information recall. The second questionnaire (only for intervention group) also measures satisfaction with the 'E-info gene ca'.

The visit will be videotaped and analysed on level of counselee participation.

Intervention

The information on the website ('E-info gene ca') is tailored to counselees' personal situation as guided by their answers on our previously developed 'QUOTE gene ca' scale. This produces different packages of pre-visit information in content, extensiveness and complexity. This information and a question prompt, a request to formulate five questions for the counsellor, may generate a variety of questions to be dealt with in the subsequent visit. E-info gene will be developed by a multi-disciplinary team of genetic counsellors, psychologists, counselees and their relatives and using recent brochures of the Dutch Cancer Society (KWF).

Study burden and risks

Previous research showed that participants do not experience being videotaped as a burden, if they are well informed on the measures taken to protect their privacy. The privacy of the participants will be assured on all prescribed manners (saving data anonimously, no other use for the video's than research, saving video's at a safe place). The video registration is done without a researcher in the consulting room. The risk for participants in this research is thus very small. The information received by the control group before the initial consult is the currently used leaflet. For the intervention group the information will be extended and aimed at optimalising the preparation of the counselee on the visit.

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

Age 18 or older
female gender
having internet access at home

Exclusion criteria

Age under 18
male gender
not having internet access at home

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):	11-02-2008
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	06-11-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
ISRCTN	ISRCTN82643064
CCMO	NL16137.041.07