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Randomised controlled trial in breast cancer genetic counseling

Submission date 26/02/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/02/2007	**Overall study status** Completed	
Last Edited 05/01/2021	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomised controlled trial in breast cancer genetic counseling

Study objectives
In 2003 over 35% of counselees at Dutch clinical genetic centres 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 personalise 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 that 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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Genetic counseling, web-based tailored info, communication, breast cancer

Interventions
The information on the website (e-info) 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 and may generate a variety of questions to be dealt with in the subsequent visit.

The e-info gene will be developed by a multi-disciplinary team of genetic counsellors, psychologists, counselees and their relatives and using recent Dutch Cancer Society (KWF) brochures.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Counselees' participation, i.e. content and amount of questions asked and information received during the visit.

Secondary outcome measures
1. Effects on expectations
1. Information recall
2. Need fulfillment
3. Satisfaction
4. Pre-post changes in breast cancer knowledge
5. Risk perception
6. Personal control
7. Cancer worry
8. (Intended) adherence to screening advices or prophylactic surgery at 12 months
9. Satisfaction with e-info gene

Overall study start date
01/09/2007

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1.Counselee for breast cancer genetic counseling
2. Age 18 or older
3. Female gender
4. Having internet access at home

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
200

Total final enrolment
197

Key exclusion criteria
1. Age under 18
2. Male gender
3. Not having internet access at home

Date of first enrolment
01/09/2007

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Netherlands Institute for Health Services Research (NIVEL)
Utrecht
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3500 BN

Sponsor information

Organisation
Netherlands Institute for Health Services Research (NIVEL) (The Netherlands)

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Sponsor type
Research organisation

Website
http://www.nivel.nl/

ROR
https://ror.org/015xq7480

Funder(s)

Funder type
Charity

Funder Name
Dutch Cancer Society (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	retraction	31/10/2012	05/01/2021	Yes	No
Results article	results	06/03/2012	05/01/2021	Yes	No