The Signal - Trial: evaluation of a screening tool for psychosocial problems in cancer genetics

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35886

Source
ToetsingOnline

Brief title
The Signal - Trial

Condition

- Other condition

Synonym
Psychosocial problems

Health condition

psychische problemen bij erfelijkheidsonderzoek voor kanker

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: KWF Kankerbestrijding (NKI 2008-4016)

Intervention

Keyword: Cancer genetics, Psychosocial problems, Randomized trial

Outcome measures

Primary outcome

The primary outcomes of the trial are: 1) increased communication on psychosocial issues, 2) counselors awareness of psychosocial problems of the counselee, and 3) management of these psychosocial problems of the counselee during and after the process of genetic counselling.

Secondary outcome

The secondary outcomes of the trial are: 1) the number of initiations of discussed problems by counselor or counselee, 2) time spent on psychosocial problems, 3) counselee and counselor*s level of satisfaction, 4) levels of counselee cancer worries, 5) number of psychosocial problems, and 6) counselee and counselor evaluation of the intervention/ feasibility of the implementation of the intervention.

Study description

Background summary

An important part of individuals undergoing genetic counseling and/or testing for cancer experience psychosocial problems and worries during or after this process. Approximately 20% of these individuals experience serious problems, such as fear for cancer in themselves or their relatives, family communication problems, unresolved grief, problems in coping with the DNA-test-results,

difficulties in choices with regard to DNA-testing, preventive surgeries, and concerns about insurance or work. Research shows that these problems are frequently undetected by the counselors. Within the limited available time of a counseling session, a lot of information should be given to the counselee. This information is mostly biomedical and provider driven. Therefore psychosocial issues can be underexposed. The use of a brief questionnaire, completed by the counselee prior to the counseling session, can serve as a tool for the counselor to screen and address the relevant psychosocial issues in a systematic manner. Therefore, in 2009-2010 we have developed and validated the *Signal-checklist* to identify relevant psychosocial problems frequently encountered in the cancer-genetics setting, and need for extra psychosocial services. This *Signal-checklist* can serve as a tool in screening systematically for psychosocial issues, addressing these issues and directing appropriate referrals to extra psychosocial services. The Signal-Trial will be performed to evaluate the use and effectiveness of the checklist.

Study objective

The aim of the trial is to evaluate the implementation of a short, self-developed cancer-genetics checklist; the *Signal-checklist*, as an aid in 1) facilitating communication on psychosocial issues during the genetic counseling session, 2) increasing counselors awareness of psychosocial problems of the counselee, and 3) improving the management of these psychosocial problems during and after the process of genetic counselling.

Study design

This study is a collaboration between the family cancer clinics of the NKI-AVL and the UMCN. Individuals requesting genetic counseling for the high incidence of cancer in their family are invited to participate in the trial. Participants will be asked to complete the *Signal checklist* prior to their counseling visit. Participants (N=200) will be randomly assigned to one of the two study arms. The intervention group will receive feed-back on the *Signal-checklist*, whereas the control group will not receive feed-back. Three weeks after the DNA-test disclosure session, participants will be asked to complete again the *Signal-checklist* followed by a telephone call by their counselor. Again, the results of the *Signal-checklist* will be available to the counselor for participants in the intervention group, but not for the control group. Both the genetic counseling session and telephone call will be audio taped. Furthermore, all participants will be asked to complete three questionnaires on the Internet (or by mail, if preferred); 1) before randomization (3 weeks prior to the counseling session), 2) three weeks after the counseling session, and 3) four months after the potential DNA-test result disclosure. These questionnaires include items on communication during genetic counseling, the need for professional psychosocial support, cancer worries, satisfaction with received care, and experiences with the use of the *Signal-checklist*. The audio-tapes

and completed questionnaires will be used to measure psychosocial problems of the counselees, the awareness of the counselors of these problems, and the management of these problems. Secondary analysis will be conducted to assess the need for extra psychosocial services, satisfaction with genetic counseling, feasibility of implementing the *Signal-checklist* and decreasing psychosocial problems over time.

Intervention

The intervention will take place twice: during genetic counseling (usually the 3rd contact with the clinic), and at follow-up (four weeks after the disclosure of the test result). The intervention comprises: 1) the completion of the *Signal-checklist* by the counselee, and 2) providing feedback by the counselor to the counselee, based on the scores at the *Signal-checklist*.

Study burden and risks

Participants will be asked to complete five questionnaires, and will have a telephone call with their counselor. We expect this to take maximally 2 hours to complete in total. With the use of the 'Signal-checklist', we expect psychosocial issues to be recognized in an earlier stage and managed properly.

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

1) between 18 and 70 years of age
2) in sufficient command of the Dutch language to complete the questionnaires
3) attendees of a second visit at the family cancer clinic because of increased risk of developing cancer due to hereditary predisposition

Exclusion criteria

Those who do not fulfill the inclusion criteria

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-10-2011
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	29-08-2011
Application type:	First submission
Review commission:	METC NedMec

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: 21151
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL37146.031.11
OMON	NL-OMON21151