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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21151

Source
Nationaal Trial Register

Brief title
Signaal-trial

Health condition

Cancer genetics
Psychosocial problems
Onco-genetica
Psychosociale problemen

Sponsors and support

Primary sponsor: Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital (NKI AVL) , University Medical Center Utrecht (UMCU)
Source(s) of monetary or material Support: Dutch Cancer Society (NKI 2008-4016)

Intervention

Outcome measures

Primary outcome

1. Increased communication on psychosocial issues, measured using an audiotape of the counseling session and telephone follow-up;

2. Counselors awareness of psychosocial problems of the counselee, measured using a checklist being completed by the counselor after the counseling session and the telephone follow-up;

3. Management of the psychosocial problems of the counselee, measured using an audiotape of the counseling session and telephone follow-up.

Secondary outcome

1. Number of initiations of discussed problems, measured using an audiotape of the counseling session and telephone follow-up;

2. Time spent on psychosocial problems, measured using an audiotape of the counseling session and telephone follow-up;

3. Satisfaction of counselor and counselee, measured using self-developed questions. Measured within the questionnaire after the counseling session and the telephone follow-up;

4. Levels of cancer worries of the counselee, assessed using the Cancer Worry Scale. Measured using the questionnaire at baseline, after the counseling session and after the telephone follow-up;

5. Number of psychosocial problems, assessed using the Signal-checklist. Measured at the intervention timepoints, and is part of the questionnaire after the telephone follow-up;

6. Feasability of implementing a questionnaire, assessed using self-developed questions within the questionnaire after the telephone follow-up.

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.

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.

This study is a collaboration between the family cancer clinics of the NKI-AVL and the UMCU. 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=260) 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.

By implementing a screening tool, communication on psychosocial issues during the genetic counseling session will be facilitated, counselors awareness of psychosocial problems of the counselee will be increased, and the management of psychosocial problems will be improved. It will result in a more counselee-oriented care. Counselees will be able to make an informed

decision during genetic counseling, preventive measures, medical screening, communicating with family relatives and living with consequences. This, in turn, will lead to a decrease in distress. If this trial shows that counselees as well as counselors benefit from the use of this new tool, future counselees will be able to benefit significantly from the availability of a tool for early detection of relevant psychosocial problems.

Study objective

Implementing the Signal-checklist and providing feed-backduring genetic counseling will:

1. Increase the number of psychosocial issues communicated during the genetic counseling session;

2. Increase the awareness of the counselor of the psychosocial problems experienced by the counselee;

3. Improve patient management, resulting in an increase of the quality of the referrals to the psychosocial service department of the hospital.

Study design

Baseline questionnaire: 3 weeks before the counseling session.

Counseling session is being audiotaped and the Signal-checklist is used measuring specific psychosocial problems.

Second questionnaire: 4 weeks after the counseling session.

Telephone follow-up is being audiotaped and the Signal-checklist is used measuring specific psychosocial problems.

Third questionnaire: 4 months after the telephone follow-up.

Intervention

The intervention will take place twice: During genetic counseling (usually the 3rd contact with the clinic), and at follow-up (three 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’.

Ad 1) The ‘Signal-checklist‘:

This checklist consists of the distress-thermometer and 26 questions addressing psychosocial problems and worries specifically relevant to those who apply for genetic counseling and testing for cancer. These questions are ordered into the following domains: 1) hereditary predisposition, 2) family- and social issues, 3) practical issues, 4) emotional issues, 5) cancer specific issues, and for those who have children: 6) children specific issues. Each domain of the checklist consists of 2 – 7 questions (26 in total). All items can be scored on a 4-point scale ranging from 0 (not at all) to 3 (a lot). The Distress Thermometer is used to measure general distress. The counselee will be asked to rate the checklist for experiences during the past week. Furthermore, for each of the domains, a question is added to assess the need for additional professional psychosocial care (response categories: yes or no). The instrument has been proven to be valid and reliable for use in clinical practice.

Ad 2) The feedback by the counselor:

The ‘Signal-checklist’ will be completed by the counselee twice: 1) one or two days before the counseling session in which the option of DNA-testing will be discussed (usually the 3rd contact at the clinic), and 2) three weeks after the release of the DNA-test results. This checklist can be completed at home via the Study-website. The results of this checklist of the intervention group will be printed on an A4-sized paper, which will be attached to the medical file by the research assistant in the morning of the counseling. The print shows a colored overview of the answers to the 26 items, which are organized in the 6 domains. Green indicates “no problem for that question/ domain”, and red “a serious problem that should be discussed during the counseling session”. To investigate the exact problem and the possible need for professional psychosocial support the item should be discussed during the counseling. The counselor will be trained in giving feedback using the outcome of the checklist in a one hour training and an additional one hour come-back training. The results of the counselees in the control group will not be available to the counselor.

The control group will not receive feedback.

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Eligibility criteria

Inclusion criteria

1. Between 18 and 70 years of age;

2. Sufficient command of the Dutch language to complete 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)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-10-2011
Enrollment:	260
Type:	Anticipated

Ethics review

Positive opinion
Date: 13-12-2011
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35886
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3057
NTR-old	NTR3205
CCMO	NL37146.031.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35886

Study results

Summary results
N/A