Cancer Genetics: Development and validity testing of a screening instrument for psychosocial problems

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To develop and evaluate a screening questionnaire as an aid in identifying individuals experiencing significant psychosocial problems associated with cancer genetic counseling. The questionnaire will be multidimensional and will be developed...

Ethical review	Approved WMO
Status	Pending
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Observational non invasive

Summary

ID

NL-OMON32510

Source
ToetsingOnline

Brief title
Development and validity testing of a screening instrument

Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Family issues

Synonym
Psychosocial problems

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cancer genetics, Psychosocial problems, Questionnaire development, Validity testing

Outcome measures

Primary outcome

The primary study parameters are the screening questionnaire and the results of

the interview between the social worker and the counselee.

The following information will be extracted from the medical records:

demographic data, number of affected relatives, age at which (s)he was first

confronted with cancer in the family, types of cancer in the family, age at

genetic testing, genetic test results, and whether (s)he has ever been treated

for cancer. Additionally, information will be collected on previous

professional psychosocial treatment and history.

Secondary outcome

not applicable

Study description

Background summary

Approximately 20% of individuals undergoing genetic counseling and/or testing for cancer experience significant psychosocial problems and worries during or after this process. These problems (i.e., generalized distress, decisional conflict, cancer worries, family communication, cancer-related grief, concerns about insurance, etc.) can be addressed effectively with professional support. However, without appropriate screening tools, 30% of counselees with psychosocial problems remain undetected in daily practice. Therefore, the development of a screening instrument in cancer genetics is warranted.

Study objective

To develop and evaluate a screening questionnaire as an aid in identifying individuals experiencing significant psychosocial problems associated with cancer genetic counseling. The questionnaire will be multidimensional and will be developed according to standardized procedures. It will be evaluated for its reliability, validity, sensitivity, specificity and positive predictive value for detecting psychosocial problems and psychosocial support needs.

Study design

The questionnaire is expected to cover three broad domains of psychosocial problems: a) general psychological problems such as anxiety and depression, b) cancer-specific problems such as fear of developing cancer (recurrence) and unresolved grief over one*s own cancer/ cancer of a close relative and c) genetic-specific problems such as decisional conflict regarding genetic testing or risk reducing options, problems in informing children and relatives about cancer risk and practical concerns (e.g. insurances). The questionnaire development process will consist of four phases according to EORTC guidelines for questionnaire module development: 1) generation of relevant issues, 2) operationalization of these issues into a set of items, 3) pre-testing the questionnaire (the first 20 participants) and 4) field testing of the resulting questionnaire*s psychometric and screening properties. The study sample will consist of new counselees (N=180) who attend the NKI-AVL family cancer clinic. During the fourth phase of the study all counselees will be invited to complete the screening questionnaire just prior to their second visit at the family cancer clinic (thus after an informative intake session), and at follow-up (three weeks after their final counseling). At both assessment points, the counselees will also be interviewed by a trained psychosocial worker who will use a semi-structured interview (*gold standard*) to determine the problem areas that warrant further services. The properties of the screening questionnaire will be evaluated with a standard set of psychometric procedures.

Study burden and risks

Study participants are invited to complete the screening questionnaire and an interview with a social worker, which will take approximately 60 minutes in total. This will take place prior to their second visit at the family cancer clinic.
Three weeks after receiving their test result, participants will be asked to complete the screening questionnare again. After filling in they will be contacted by phone to have an interview with a social worker. This will take approximately 60 minutes in total. There is no specific benefit or burden for the participant because of their participation in the study.

The screening instrument developed during this study will facilitate efficient

and timely identification of individuals undergoing cancer genetic counseling who are in need of psychosocial services or suffer from specific psychosocial problems that may require additional professional support. This, in turn, can facilitate appropriate planning and provision of psychosocial services within the family cancer clinic context. The availability of this screening instrument will set stage for future intervention studies aimed at decreasing onco-genetic related psychosocial problems or to investigate the effectiveness of the instrument measuring communication between counsellors and clients, the awareness of clients* problems, appropriate counseling behaviour and correct referrals which should lead to an increase in health related quality of life.

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 not fulfill the inclusion criteria

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2009
Enrollment:	180
Type:	Anticipated

Ethics review

Approved WMO

Date:	10-02-2010
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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
CCMO	NL29969.031.09