Phase 1-3 development of a questionnaire for assessing sexual health in cancer patients: A cross cultural project of the EORTC Quality of Life Group

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON40154

Source
ToetsingOnline

Brief title
Development of an EORTC QOL Sexual Health module

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified
- Sexual dysfunctions, disturbances and gender identity disorders
- Sexual function and fertility disorders

Synonym
Cancer

Research involving
Human

Sponsors and support

Primary sponsor: Medical University Graz
Source(s) of monetary or material Support: EORTC QoL groep

Intervention

Keyword: Cancer survivorship, Quality of life, Rehabilitation after cancer, Sexual health

Outcome measures

Primary outcome

see study design

Secondary outcome

See study design

Study description

Background summary

Cancer and cancer therapies are frequently associated with sexual dysfunction. Across sites, estimates of sexual dysfunction after various cancer treatments have ranged from 40% to nearly 100%. Research suggests that about 50% of women who have had breast or gynecologic cancer experience long-term sexual dysfunction including vaginal changes or urological symptoms; and for men with prostate cancer, erectile dysfunction has been the primary form of sexual dysfunction investigated. Meta-analysis showed that nearly 70% of men who have been treated for prostate cancer experience long-term sexual dysfunction. The most common sexual problems for people who have cancer are loss of desire for sexual activity in both men and women, problems achieving and maintaining an erection in men, and pain with intercourse in women.

Unlike many other physiological side effects of cancer treatment, sexual problems do not tend to resolve within the first year or two of disease-free survival rather, they may remain constant and fairly severe or even continue to increase. Long-term effects of different treatment on sexual functioning have been studied in cervical cancer survivors. Existing research has focused on women who have breast or gynecologic cancer and men who have prostate cancer.

Less is known about how other types of cancers affect sexuality. Although it is unclear how much sexual problems influence a survivor*s rating of overall health-related quality of life, these problems are clearly bothersome to many patients and interfere with a return to normal post-treatment life.

Study objective

The aim of this project is to develop a comprehensive EORTC questionnaire for assessing sexual health for male and female patients with cancer. Given the lack of a sexual health related measure that can be used in clinical trials and in clinical praxis the decision has been made to develop a *stand-alone* sexual health questionnaire according to the EORTC QLG guideline (Blazeby et al. 2002). Since this sexual health measure should be applicable to all cancer patients, and the literature review showed that not all cancer sites were well-represented, it is necessary to include a broad range of cancer patients with different cancer sites.

In each country a list of issues will be administered to a sample of male and female cancer patients with different cancer sites. Both newly diagnosed patients under treatment and in post-treatment follow-up will be interviewed. When selecting the patients for interviews, care will be taken to ensure a balanced patients group covering the major cancer sites as well as rarer disease sites

Study design

The development of the EORTC Sexual Health questionnaire is done according to standard procedures for EORTC QoL questionnaire development -
phase 1: Literature review: a comprehensive review of the literature has already been conducted resulting in a list of 126 issues.
By use of patient and HCP interviews the list of issues is reduced according to priority ratings. On the basis of both - patients and HCPs response - the list of sexual health issues will be adapted. Decisions on which issues to keep or delete will be made using the EORTC module development guidelines and decision rules (Blazeby et al. 2002).
phase 2: the list of issues will be operationalised into items. The QLG Item Bank, existing EORTC modules, and other questionnaires reviewed for items that deal with the selected issues will be searched. Remaining issues will be converted into novel items in a style and format compatible with the EORTC QLQ assessment system, and any necessary translations will be carried out following EORTC QLG Translation Guidelines (Cull et al 2002).
Phase 3: In phase 3 the sexuality items will be pre-tested to identify and solve potential problems (e.g. terminology, phrasing) and to determine the need for additional questions or the elimination of items. Patient interviews will be conducted to assess relevance and priority of each item in the provisional questionnaire (Appendix 3). A broad range of patients with different cancer

sites and treatment modalities will be approached. Patients with different cancer sites under first line treatment or post-treatment follow up will be included. Following the EORTC QLG Guidelines for questionnaire development patients will be asked to rate the relevance and priority of each item on a four-point scale. They will be asked to suggest any relevant items which were not included in the list or to delete items that are irrelevant. The items will be used to check content validity. The feedback of patients will help to refine the conceptual mode. This approach will provide assurance that the QLG objectives of Phases 1 and 2 have been met.
We will aim for 15 patients diagnosed with various cancer sites in 11 countries. This will result in a total sample of 165 interviews (15 patients x 11 countries = 165). Care will be taken to ensure a balanced patients selection covering the major cancer sites as well as rarer disease sites. A debriefing questionnaire to assess the wording of items and check for omissions or redundancy will be completed. Clinical and socio-demographic data will be collected from each patient.

Study burden and risks

Burden: competion (10 mins) of a questionnaire involving sexuality issues, and a short debriefing interview.

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

In each country the reduced list of issues will be administered to a sample of male and female cancer patients with different cancer sites. Both newly diagnosed patients under treatment and in post-treatment follow-up will be interviewed. When selecting the patients for interviews, care will be taken to ensure a balanced patients group covering the major cancer sites as well as rarer disease sites

Exclusion criteria

Insufficient command of written and oral English

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-12-2013
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	29-11-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	05-09-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	17-10-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL45961.058.13