An international field study for the reliability and validity of the EORTC Sexual Health Questionnaire (EORTC SHQ-C22) for assessing sexual health in cancer patients.

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The aim of this international field study is to test the scale structure, reliability, responsiveness to change and validity of the EORTC SHQ-C22 in patients with different cancer diagnoses, at different stages of disease, and with different...

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

Summary

ID

NL-OMON43354

Source
ToetsingOnline

Brief title
EORTC Sexual Health Questionnaire

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
seksual problems after cancer treatment, Sexual health, sexuality

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cancer survivorship, Quality of life, Sexual health, Sexuality and cancer

Outcome measures

Primary outcome

The primary endpoint of the study is to confirm the hypothesized scale

structure of the EORTC SHQ-C22.

Secondary outcome

Scale Structure, Reliability, Convergent validity, Known-group comparisons,

Responsiveness to change analysis

Study description

Background summary

The EORTC Quality of Life Group established standardized guidelines for developing questionnaires20: (1) generation of QoL issues aiming to identify issues relating to sexual health in patients diagnosed with different cancer sites, (2) operationalisation to derive modifications to the preliminary module using a structured interview method, and (3) pre-test the preliminary questionnaire module in order to identify and solve potential problems in the administration and to determine the need for additional questions or the elimination of questions. The process of translation follows a rigorous forward-backward procedure according to the EORTC translation guidelines. The diagnosis and treatment of cancer causes significant physical, psychological, and social effects that interfere with a person*s sexuality. Sexuality is complex and broadly defined concept comprising: the sexual response cycle, body image, ones* sexual role and sexual relationships. Several EORTC cancer site specific modules include a limited number of sexual functioning items that do not adequately cover the whole range of sexual health which are most important for cancer patients. The EORTC Sexual Health Questionnaire * Cancer (EORTC SHQ-C22) was developed as a standalone measure

following the standard phase 1-3 procedures. Five multi-item scales (Sexual response, side-effects influencing sexual activity, relationship, global sexual health, male sexual health issues, and female sex health issues) and one single scale (communication with health care professionals concerning sexual health) are proposed.
The EORTC SHQ-C22 has been developed as a stand-alone measure to assess sexual health of cancer patients. The questionnaire can be used in all treatment options (surgery, chemotherapy, radiotherapy, targeted therapy) and all settings of health care (acute care, palliative care, rehabilitation). Thus, it is applicable for all cancer diagnosis as well as all phases and stages of cancer. The SHQ-C22 is designed in a way that it can be used as a single measure or in conjunction with the EORTC QLQ-C30

Study objective

The aim of this international field study is to test the scale structure, reliability, responsiveness to change and validity of the EORTC SHQ-C22 in patients with different cancer diagnoses, at different stages of disease, and with different treatment modalities. We will investigate the cross-cultural applicability and acceptability, scale structure, reliability, including test-retest and internal consistency, construct, divergent and convergent validity (know-group comparisons), and sensitivity to change.

Study design

For patients in Group A and B a second assessment will be performed when patients return to the hospital for a follow-up visit (Group A) or during treatment (Group B). For test-retest patients in Group D will be asked to complete the EORTC QLQ-C30, the SHQ-C22 for a second time seven days after the first assessment. The questionnaires will either be sent in the post or participants may take them home after the first appointment. A prepaid envelope will be supplied and patients will be asked to return the completed questionnaires to their local investigator. If this second assessment is not mailed back within 14 days after the follow-up interview, one reminder will be made by telephone call.

Study burden and risks

Completing a questionnaire twice (about 15 mins each time) and a short debriefing questionnaire, in which the questions involve intimate, private, sexual aspects of the participant's personal 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

The study sample will be composed of a consecutive series of cancer patients who meet the study eligibility criteria in each participating centre. Study participants will be enrolled in four groups: Group A: Patients undergoing surgery alone Group B: Patients who receive chemotherapy and/or radiotherapy and/or endocrine therapies as first line treatment with curative intention Group C: Patients who receive palliative treatment (any treatment) Group D: Patients with no evidence of disease who have completed treatment for at least 6 months up to 5 years (test-retest) The SHQ-C22 will be used in patients from across all cancer sites and stages. Sampling will be on the basis of gender, age, primary cancer diagnosis and treatment. Inclusion criteria: a) Histological confirmed diagnosis of cancer (primary, recurrent or metastatic disease) b) Any tumour site and stage c) Mentally fit to complete the questionnaires d) Able to understand the language of the questionnaires e) 18 years of age or above f) Patient is willing to give informed written consent

Exclusion criteria

Patients participating in other QoL studies that might interfere with this study b) Patients who are unable to self-complete the questionnaires

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):	04-10-2016
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	21-06-2016
Application type:	First submission
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	NL57543.058.16