

The consequences of colorectal cancer for patients and their partners

Published: 17-05-2010

Last updated: 15-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational non invasive

Summary

ID

NL-OMON36622

Source

ToetsingOnline

Brief title

The consequences of colorectal cancer for patients and their partners

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym

Colorectal cancer, Colorectal carcinoma, Intestinal cancer

Research involving

Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis

Source(s) of monetary or material Support: KWF fonds

Intervention

Keyword: Health status, Personality, Quality of life, Sexual functioning

Outcome measures

Primary outcome

Primary study parameters: Subjective sexual functioning, objective sexual functioning

Outcome of the study: Quality of (sexual) life, health status

Secondary outcome

Secondary study parameters: Personality, mood states (anxiety/depression)

Outcome of the study: Quality of (sexual) life, health status, healthcare needs

Study description

Background summary

The results of this prospective study will give insight in 1) the incidence of sexual problems and the extent patients with colorectal cancer are bothered by these problems across time, 2) the effect of different treatment options on sexual functioning, 3) the relation between sexual problems and quality of life, and 4) the determinants of sexual problems and quality of sexual life adopting the biopsychosocial approach of patients with colorectal cancer who have been treated with surgery, radiation and/or chemotherapy, and more specifically to the role of personality and partner factors and sexual functioning/quality of sexual life, 5) the healthcare needs of patients and their partners with regard to sexuality and intimacy.

Study objective

This study will contribute to improving quality of care for cancer survivors, since sexual problems seem to be profound but not always discussed with patients. Patients are now often insufficiently informed and do not know how to interpret their early and long-term physical or psychosocial problems. Characterizing the sexual problems of colorectal cancer patients and their partners and identifying factors that may alleviate the adverse effects of sexual dysfunction. Knowledge of potential future problems in sexual function

should be incorporated into preoperative counselling and guiding treatment decisions. In this way, patients are allowed to make better informed decisions about the management of colorectal cancer. Sexual dysfunction may significantly impact patient's subsequent quality of life. Knowledge about sexual problems is essential in order to educate both health professionals and patients about potential problems after medical treatment. However, as sexuality can be seen as a multidimensional construct, the development of psychosocial interventions will also benefit.

Study design

Patients who are diagnosed with colorectal cancer at one of the participating hospitals during the period May 2010 and May 2014, and their partners will be asked to participate. Participants will be asked to complete questionnaires on sexual functioning, quality of life, fatigue, depressive symptoms, personality factors, and demographic factors. Questionnaires will be completed before surgical treatment or preoperative radiotherapy and at 6 weeks, 3, 6, and 12 months after diagnosis. Questionnaires on demographic and personality factors will only be filled in at baseline.

500 patients will be included within 2 years

A subgroup of patients and their partners will be asked to participate in separate focus group interviews. The participants will be purposively selected from their participation in the larger prospective study. In addition, we want to recruit couples of whom the patient has been diagnosed with colorectal cancer between 2008 and 2010, to ensure a wide variety of experiences to be represented. The focus group meetings are designed to assess the healthcare needs of patients and their partners with regard to sexuality and intimacy and how these healthcare needs can be best addressed. Furthermore, in order to investigate possible discrepancies between couples coping with colorectal cancer and their healthcare professionals we additionally want to conduct a focus group meeting with healthcare professionals in order to explore how they perceive the healthcare needs of couples coping with colorectal cancer and how these healthcare needs can be best addressed. There will be two focus groups consisting of patients (n=10 per group), two focus groups in which the partners will participate (n=10 per group), and one focus group in which the healthcare professionals will be interviewed (n=10). Each focus group will take 90 minutes.

Study burden and risks

Burden: 4 hours / 5.5 hours (depending on participation in the focusgroup meeting)

Risks: not applicable

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

Patients diagnosed with colorectal cancer and their partners.

Exclusion criteria

Recurrence of disease at baseline; poor expression of the dutch language; dementie; a history of psychiatric illness.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-09-2010

Enrollment: 1000

Type: Actual

Ethics review

Approved WMO

Date: 17-05-2010

Application type: First submission

Review commission: METC Brabant (Tilburg)

Approved WMO

Date: 23-08-2010

Application type: Amendment

Review commission: METC Brabant (Tilburg)

Approved WMO

Date: 23-03-2011

Application type: Amendment

Review commission: METC Brabant (Tilburg)

Approved WMO

Date: 30-08-2011

Application type: Amendment

Review commission: METC Brabant (Tilburg)

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: 27180

Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL32121.008.10
OMON	NL-OMON27180