Sexual functioning and the quality of sexual life in patients with colorectal cancer and their partners.

No registrations found.

Ethical review Positive opinion

Status Pending

Health condition type -

Study type Observational non invasive

Summary

ID

NL-OMON27180

Source

Nationaal Trial Register

Health condition

Sexual function, Sexal dysfunction, Quality of (sexual) life, Colorectal cancer

Sponsors and support

Primary sponsor: Tilburg University

Source(s) of monetary or material Support: Dutch Cancer Society

Intervention

Outcome measures

Primary outcome

The objectives of this study will be to examine:

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 association between sexual problems and quality of life;
- 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.

Secondary outcome

N/A

Study description

Background summary

N/A

Study objective

Sexual dysfunction is present, to some extent, in most patients after the treatment for colorectal cancer.

There is a relationship between both treatment-related (e.g., type of surgery) and psychosocial factors (e.g., depressive symptoms) and sexual dysfunction, the quality of sexual life and the partnerrelationship.

Study design

Questionnaires are completed before treatment (T0), 6 weeks (T1), 3 months (T2), 6 months (T3), and 12 months (T4) after treatment.

Intervention

Patients will receive care as usual. Participants and their partners will complete several questionnaires (e.g., sexual functioning, depressive symptoms, quality of life, personality) before treatment (T0), 6 weeks (T1), 3 months (T2), 6 months (T3), and 12 months (T4) after treatment.

Contacts

Public

Postbus 90153

M.J. Traa

Warandelaan 2

Tilburg 5000 LE

The Netherlands

+31 (0)13 4664129

Scientific

Postbus 90153

M.J. Traa

Warandelaan 2

Tilburg 5000 LE

The Netherlands

+31 (0)13 4664129

Eligibility criteria

Inclusion criteria

- 1. Patients who are diagnosed with colorectal cancer in one of the participating centra, and their partners are asked to participate in this study prior to treatment;
- 2. Patients have to be between 18 and 75 years old.

Exclusion criteria

- 1. Disease recurrence at baseline or metastases:
- 2. Poor expression in the Dutch language;
- 3. Dementia;
- 4. History of psychiatric illness.

Study design

Design

Study type: Observational non invasive

Intervention model: Parallel

Allocation: Non controlled trial

Control: N/A, unknown

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 15-03-2010

Enrollment: 600

Type: Anticipated

Ethics review

Positive opinion

Date: 12-10-2010

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36622

Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register ID

NTR-new NL2452 NTR-old NTR2568 Register ID

CCMO NL32121.008.10

ISRCTN wordt niet meer aangevraagd.

OMON NL-OMON36622

Study results

Summary results

N/A