Sexual complaints in female cancer survivors: Is there a need for treatment?

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Observational multicenter trialThe following research questions (Q) will be addressed in patients (and partners) (Q1) whether sexual problems as reported by female cancer survivors are personally distressing and if so, (Q2) what are possible...

Ethical review Approved WMO **Status** Recruitment stopped

Health condition type Sexual dysfunctions, disturbances and gender identity disorders

Study type Observational non invasive

Summary

ID

NL-OMON36267

Source

ToetsingOnline

Brief title

Sexual complaints in female cancer survivors: need for treatment?

Condition

- Sexual dysfunctions, disturbances and gender identity disorders
- Obstetric and gynaecological therapeutic procedures

Synonym

sexuxal complaints

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: KWF Kankerbestrijding & Stichting Alpe

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☐Huzes (UL 2010-4760)

Intervention

Keyword: cancer, sexual complaints, treatment, women

Outcome measures

Primary outcome

sexual complaints, sexual distress and needs

Secondary outcome

treatment, somatic and psychological variables

Study description

Background summary

Observational multicenter trial

Rationale: About half of the women treated for cervical cancer do report long-term sexual complaints, which may be personal distressing in about 25% of these women. Sexual rehabilitation for female cancer survivors lags far behind that provided for men. There is an urgent need to develop suitable interventions for sexual complaints in women. In our clinical experience, however few women with sexual complaints after cancer treatment seek treatment for their complaints. Reasons for not seeking help for sexual complaints reported in the literature are (1) not experiencing sexual complaints as distressing and (2) barriers in clinical practice to discuss sexual issues. Therefore, we first want to conduct a needs assessment study in patients, before we decide to develop and evaluate a sexual rehabilitation program for female cancer survivors.

Qualitative study

Purpose: The main purpose of this study is to deepen and broaden the insights that are gained from the observational multicenter trial study that is currently being conducted.

Study objective

Observational multicenter trial

The following research questions (Q) will be addressed in patients (and partners) (Q1) whether sexual problems as reported by female cancer survivors are personally distressing and if so, (Q2) what are possible barriers in

clinical practice to seek treatment for these complaints, and (Q3) whether there is a need for (specific) treatment interventions. By including both patients and their partners in the current study, we hope to identify facilitating and limiting factors relevant for the development and evaluation of a sexual rehabilitation program.

Qualitative study

The aims of this study are (Q1) to obtain insight in the development and course of sexual dysfunctions and distress since the cancer diagnosis and treatment; (Q2) to assess CC survivors* attitudes towards sexual health care and information provision; (Q3) to identify CC survivors* experiences and/or needs in terms of information and health care provision; (Q4) to address Health Belief Model variables (and aspects mentioned by the participants) with respect to cervical cancer survivors* help seeking behavior; and (Q5) to gain insight into the partners* perspective with respect to the impact of SD and sexual distress on the relation, the impact of having a care taking role on the sexual relationship, and his/her sexual health care and information needs.

Study design

Observational multicenter trial

A survey (sexual complaints, personal distress; help-seeking behavior; treatment suggestions) in a multicenter observational study.

Qualitative study

Semi-structured interviews will be conducted with women with a history of cervical cancer who perceive sexual distress, and their partners.

Study burden and risks

Observational multicenter trial

Participants will complete questionaires about personal themes, which may be of some discomfort for some of the participants. The total duration to complete the questionnaires will be about 60 min. There will be no benefits for the participants.

Qualitative study

Participants will be interviewed about personal themes, which may be of some discomfort for some of the participants, while other participants might experience discussing this topic as relieving. The interview will last 60 tot 120 minutes.

Contacts

Public

Academisch Medisch Centrum

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Scientific

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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 will be recruited by reviewing medical files, collected prospectively in databases, of women who have undergone a treatment for early stage cervical cancer in the period 2000-2009.

Exclusion criteria

signs or recurrent metastatic cervical cancer, no follow-up due to living abroad; insufficient knowledge of the Dutch language.

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): 01-07-2011

Enrollment: 550

Type: Actual

Ethics review

Approved WMO

Date: 31-03-2011

Application type: First submission

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO

Date: 22-12-2011

Application type: Amendment

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO

Date: 14-03-2012

Application type: Amendment

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO

Date: 23-08-2012

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 NL35147.058.10