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 d□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

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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