Women*s experiences with vaginal dilator use following radiotherapy for gynaecological cancer: a qualitative study.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive neoplasms female benign
Study type	Observational non invasive

Summary

ID

NL-OMON39081

Source
ToetsingOnline

Brief title
Vaginal dilator use after radiotherapy for gynaecology cancer

Condition

- Reproductive neoplasms female benign
- Sexual dysfunctions, disturbances and gender identity disorders
- Sexual function and fertility disorders

Synonym
gynaecological oncology

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 2011-5245)

Intervention

Keyword: dialator therapy, gynaecological cancer, radiotherapy, sexual complaints

Outcome measures

Primary outcome

Sexual functioning, Sexual distress, Experiences with vaginal dilation therapy,

Sexual rehabilitation after RT, Acceptability/Understandability of the

information booklet.

Secondary outcome

Treatment, Somatic and Psychological variables

Study description

Background summary

In the Netherlands, more than 4000 women are diagnosed with gynecological cancers annually, and 40% will receive pelvic radiotherapy (RT) with or without brachytherapy (BT) as primary or post-surgical treatment. Gynecological cancer treatment, RT combined with BT in particular, have been shown to be associated with high rates of sexual problems such as reduced sexual interest and satisfaction, pain during intercourse and vaginal symptoms (dryness, shortening and/or tightening). Regular use of vaginal dilators reduces the risk of vaginal fibrosis and stenosis after RT, and has become established practice worldwide. Despite the proposed benefits of dilation therapy, many women have difficulties following the instructions and/or fail to use vaginal dilators regularly.

Study objective

By investigating reasons for (non-)compliance with vaginal dilation in a sample of gynecological cancer patients receiving RT, we hope to identify facilitating and limiting factors relevant for the development of a sexual rehabilitation

program. Another purpose of the current study is to evaluate the patient information booklet for the sexual rehabilitation on comprehensibility, satisfaction with information and content.

Study design

A qualitative multicenter study in women with (a history of) gynecological cancer who received RT and BT. A maximum of 25 women with be interviewed about reasons for (non-) compliance with vaginal dilation. Ten of these women will be asked to also evaluate the information booklet about sexual issues and benifits of dilator use.

Study burden and risks

Participants will be asked questions about personal themes, which may be of some discomfort for some of the participants. The total duration of each interview will be 60 minutes maximum. There will be no risks for the participants.

Contacts

Public
Academisch Medisch Centrum

Albinusdreef 2
Leiden 2300 RC
NL
Scientific
Academisch Medisch Centrum

Albinusdreef 2
Leiden 2300 RC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Women will be invited to participate in the current study if they have been treated with primary radiation therapy between 6 and 24 months previously, were sexually active before their cancer diagnosis, and are consenting to being interviewed about vaginal dilation and sexuality. A selection of ten of these women (who have indicated to be willing to participate in future studies)will be made to evaluate the information booklet.

Exclusion criteria

Signs of recurrent or metastatic cancer, insufficient knowledge of the Dutch language, or living abroad.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-04-2013
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	19-09-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	25-04-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL41267.058.12