A nurse-led sexual rehabilitation programme for women with gynaecological cancers receiving radiotherapy: a randomized multicentre trial.

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Ethical review	Approved WMO
Status	Completed
Health condition type	Sexual function and fertility disorders
Study type	Interventional

Summary

ID

NL-OMON55440

Source
ToetsingOnline

Brief title
Sexual rehabilitation Program After Radiotherapy for gynaecological Cancers

Condition

- Sexual function and fertility disorders

Synonym
sexual complaints, sexual problems

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: KWF/Alpe d'HuZes;Bontius Stichting

Intervention

Keyword: Gynaecological Cancer, Radiotherapy, Sexual rehabilitation, Vaginal dilation therapy

Outcome measures

Primary outcome

The primary outcome is sexual functioning 12 months after radiotherapy.

Secondary outcome

The secondary outcomes include: sexual functioning 24 months after

radiotherapy, vaginal symptoms and body image concerns, fear of coital and

non-coital sexual activity, sexual distress, treatment-related distress,

generic health-related quality of life related to gynaecological cancer,

psychological distress, relationship dissatisfaction, frequency of dilator use,

and vaginal physical symptoms.

Study description

Background summary

In the Netherlands, more than 4000 women are diagnosed with gynaecological cancers (GC) annually, of whom 30-40% receive primary or postoperative pelvic radiotherapy (RT), often combined with brachytherapy (BT). GC treatment and RT in particular, is associated with high rates of sexual problems, such as pain during intercourse, and vaginal symptoms (dryness, shortening and/or tightening). In cooperation with the relevant end-users in the Netherlands, we developed a nurse-led sexual rehabilitation intervention directed at increasing knowledge and coping strategies of patients (and their partners if available) regarding sexual issues after RT and benefits of and compliance with dilator use after RT+BT. The intervention has been pilot-tested at two university

medical centres (P13.102). Most patients reported that the intervention was helpful in resuming their sexual relationship. The nurses reported that they had sufficient expertise to support the participants during sexual rehabilitation and vaginal dilator use. Based on these findings, we concluded that this intervention was feasible and applicable in clinical practice.

Study objective

In this study, we evaluate the efficacy of a sexual rehabilitation programme in improving the sexual functioning of women who are treated with radiotherapy for gynaecological cancer. The rehabilitation programme is compared to optimal regular care (i.e., oral and written information about sexual functioning after radiotherapy for gynaecological cancer, and one-time education/information by the radiotherapist-oncologist and/or oncology nurse).

Study design

Women with gynaecological cancer (N = 220), who are treated with radiotherapy in one of the participating Gynaecological Cancer Centres, are randomized to either the intervention- or control group. Stratification variables included in the randomization are treatment (RT+BT vs. RT only women) en having a partner (yes/no). Women in the control group receive 'optimal regular care', which includes oral and written information about sexual problems after gynaecological cancer and one-time education/information by the radiotherapist-oncologist and/or oncology nurse). Women in both the intervention- and control group complete study assessments at baseline, and 1 month, 3 , 6, 12 and 24 months after radiotherapy.

Intervention

Women in the intervention group receive information about sexual rehabilitation after gynaecological cancer (a brochure and website) and guidance in sexual rehabilitation from an oncology-nurse by means of four appointments (1, 3, 6 and 12 months after radiotherapy). Women who are treated with RT+BT, receive an extra appointment with the nurse in order to provide these women with additional support in the usage of the vaginal dilators to prevent stenosis. This sexual rehabilitation programme aims to increase the understanding of and compliance with the instructions to use vaginal dilators. Oncology nurses conduct the intervention after a 50-hour training in sexology and cognitive

behavioural interventions. The oncology nurses are supervised by trained psychologists/sexologists. The control group receives 'optimal regular care', which consists of the same information that is given to the intervention group and one-time education by the radiotherapist-oncologist and/or oncology nurse.

Study burden and risks

Participating in this study will not cause any (physical) harm for the participants. Participants will be asked to fill in online questionnaires six times (30-40 minutes per assessment).and the radiotherapist will measure the vagina during the control visits (5x). Completion the questionnaires may cause some discomfort because of the subject and the time investment they have to make.

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

The study population will be composed of 220 women, who 1) are 18 years or older, 2) will be treated with radiotherapy for gynaecological cancer and who 3) wish to retain sexual activity on the short- or long-term. The study sample will consist of women who will be treated with RT or RT+BT for gynaecological cancer:
• RT: Postoperative pelvic external beam radiotherapy for cancer of the cervix, vagina or endometrium.
• RT+BT: either primary or postoperative pelvic external beam radiotherapy for cancer of the cervix, vagina or endometrium with a brachytherapy boost by intra-uterine and/or vaginal brachytherapy; this includes treatment with RT+BT for local relapse after previous surgery for cervix, vaginal or endometrial cancer.

Exclusion criteria

Women will be excluded from the study if they: 1) are living abroad during follow-up; 2) have insufficient knowledge of the Dutch language; 3) have major psychiatric disorders (i.e., major affective disorder, psychotic disorder, substance abuse related disorder, or posttraumatic stress disorder resulting from abuse in the area of the pelvic floor and genitals (e.g. sexual abuse)).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	07-08-2018
Enrollment:	220

Type:	Actual

Ethics review

Approved WMO Date:	05-03-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	24-09-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	24-08-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	31-01-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	29-10-2021
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

ID: 20908
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL62767.058.17
Other	NTR7175 en NCT03611517
OMON	NL-OMON20908