SPARC study; sexual rehabilitation after radiotherapy for gynaecological cancers

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20908

Source
Nationaal Trial Register

Brief title
SPARC

Health condition

gynaecological; cancer; carcinoma; gynaecologische; kanker; carcinoom; cervical; cervix; baarmoederhals; vagina; vaginal; endometrial; endometrium; baarmoederslijmvlieskanker;

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: KWF/Alpe d'HuZes

Intervention

Outcome measures

Primary outcome

The primary outcome measure is sexual functioning and will be assessed with the 19-item Female Sexual Function Index (FSFI).

We expect that the intervention condition will have a significantly higher score on the FSFI at

12 months post RT(BT), with a medium effect size (Cohen’s d=0.5), This corresponds with a difference of 3.2 points on the FSFI total score, with a standard deviation of 6.4.

Secondary outcome

Vaginal symptoms and body image concerns are assessed with the Gynaecological Cancer Module (QLQ-CX24) of the Dutch version of the European Organization for Research and Treatment of Cancer (EORTC).

Fear of coital and non-coital sexual activity are assessed with the 8–item Fear of Sexuality Questionnaire (FSQ).

The level of sexual distress is assessed with the 12-item Female Sexual Distress Scale (FSDS).

Treatment related distress is assessed with the 15-items Impact of Event Scale-revised (IES-R).

Generic health-related quality of life related to gynaecological cancer is assessed with the Dutch version of the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire Core 30 (QLQ-C30).

Psychological distress is assessed with the 14-item Hospital Anxiety and Depression Scale (HADS).

Relationship dissatisfaction is assessed with the 10-item relationship dissatisfaction subscale of the Maudsley Marital Questionnaire (MMQ).

Vaginal physical symptoms will be assessed during physical examination (by the radiation oncologist) by standardized clinical examination: grade of mucosal atrophy, dryness, fibrosis, and signs of vaginal shortening and/or stenosis

Patients treated with RTBT will in addition complete a short questionnaire regarding the frequency of dilator use during the previous month.

Cost-effectiveness: the Dutch tariff for the EQ-5D-5L will be assessed for cost-effectiveness analysis.

Study description

Background summary

SUMMARY

Rationale: 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 (RTBT). GC treatment and RT/RTBT 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 professionals and patient advocates in the Netherlands, we developed a nurse-led sexual rehabilitation intervention to increase 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 RTBT. The intervention has been pilot-tested at two university medical centres (CME LUMC P13.102). Most patients reported that the intervention was helpful in resuming their sexual relationship. The nurses reported (after undergoing a specific 50 hour-training and receiving supervision of a psychologist/sexologist) that they had sufficient expertise to support the participants during sexual rehabilitation and vaginal dilator use. It was concluded that this intervention was feasible and applicable in clinical practice, and should be tested in a randomised controlled trial in a larger group of patients.

Objective: The primary aim is to evaluate if the nurse-led sexual rehabilitation intervention improves sexual recovery and functioning in GC patients after RT compared with usual care. Study design: Women with GC (n=220) who receive RT in one of the participating GC centres (n=9) will be randomized to either the nurse-led sexual rehabilitation intervention or usual care, stratified for combined RTBT (n=110) vs. RT alone (n=110) and having a partner (yes/no). Participants are asked to complete questionnaires at baseline and 1, 3, 6, and 12 months after completion of RT.

Study population: Women who will be treated with RT for gynaecological cancer and who wish to retain their sexual activity on the short and/or long term.

Intervention (if applicable): The intervention consists of four one-hour sessions with the oncology nurse at 1 month, 3, 6, and 12 months after RT. Women who received RTBT will receive an additional appointment with the nurse (2 months after RTBT) to promote regular use of vaginal dilators in order to prevent stenosis. Oncology nurses conduct the intervention after a 50-hour training in sexology and cognitive behavioural interventions.

Main study parameters/endpoints: Primary endpoint is sexual functioning at 12 months post-RT and/or BT); secondary endpoints include: vaginal symptoms and body image concerns, fear of
(non-)coital sexual activity, treatment-related distress, psychological and sexual distress, generic-related health related to gynaecological cancer, relationship satisfaction, frequency of dilator use, and vaginal physical symptoms (assessed during physical examination by the radiation oncologist). The cost-effectiveness of the intervention will also be evaluated.

Study objective

Given the high prevalence and burden associated with sexual problems and the existence of barriers to seek treatment among gynaecological cancer patients, there is a clear need for a

brief, inexpensive and effective psychosexual rehabilitation intervention. We expect women who receive the nurse-led sexual rehabilitation programme to report a greater improvement in sexual functioning from immediate post-radiotherapy to 1 year post-radiotherapy than women in the control group.

Study design

The primary outcome (FSFI) will be assesed at baseline (before randomisation), 1, 3, 6, and 12 months post-RT(/RTBT).

The secondary outcome measures will be completed at 1, 3, 6, and 12 months after RT. The level of sexual distress (FSDS) is also assessed at baseline.

Physical examination will take place at baseline, and at 1, 3, 6 and 12 months after completion of treatment.

The questionnaire regarding the frequency of dilator use will be assessed at 1, 3, 6, and 12 months.

Intervention

Intervention group: the nurse-led sexual rehabilitation programme will consist of four couple (or patient) sessions of a maximum of 60 minutes each, during the 12 months following RT. The sessions will be scheduled at 1 month, 3, 6- and 12 months after RT. Patients treated with RTBT will have an additional session at 2 months after RT. Furthermore, if preferred, patients and therapists can schedule one follow-up session/telephone consultation of 30 minutes between 6 and 12 months after RT. The nurse-led intervention will include (1) educating patients (and their partners) about the specific cancer diagnosis and treatment, (2) education on the importance of regular dilation for prevention of vaginal stenosis (if indicated), (3) discussing and resolving potential experienced barriers to perform new behaviour, such as dilation (if indicated) and lubricant use, and fear of penetration with dilators (if indicated) or fear of resuming sexual activity after cancer, (4) promoting couples' mutual coping and support processes and (5) specific sexual therapy techniques to address sexual and body image concerns. Partners will be requested to participate in the sessions. The intervention offers a framework that allows individualization of treatment depending on patient-specific psychological, relational and somatic factors

Control group: Optimal 'care as usual'. Although 'care as usual' cannot be completely

standardized, it will not involve a nurse-led intervention. This will slightly vary according to each participating hospital's guidelines and the patients' preference. However, since the Dutch guidelines suggest that information and dilators (if indicated) have to be recommended to all patients, and the information booklet 'Sexuality after pelvic radiation for gynaecological cancer: Information for women and their partners' has already been shown useful, all participants of the CAU condition will, as an optimal standard, be provided with the booklet, and a vaginal dilator set (if indicated), free of costs.

The patient information is also available on a website.

Contacts

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Eligibility criteria

Inclusion criteria

Women (1) who will be treated with radiotherapy (2); external beam radiotherapy (RT) or external beam radiotherapy with a brachytherapy boost (RTBT) for cancer of the cervix, vagina, or endometrium (3). Women have to be 18 years or older (4) and wish to retain sexual active on the short or long term (5).

Exclusion criteria

Living abroad during follow-up (1), major affective disorder (2), psychotic disorder (3), substance abuse related disorder (4), posttraumatic stress disorder resulting from abuse in the area of the pelvic floor and genitals (5), and insufficient knowledge of the Dutch language (6).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-08-2018
Enrollment:	220
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-04-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55440
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6986
NTR-old	NTR7175
CCMO	NL62767.058.17
OMON	NL-OMON55440

Study results