SPARC study; sexual rehabilitation after radiotherapy for gynaecological cancers

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20908

Bron
Nationaal Trial Register

Verkorte titel
SPARC

Aandoening

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

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC)
Overige ondersteuning: KWF/Alpe d'HuZes

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

P.O. BOX 9600
M.M ter Kuile,
Department of Gynaecology, Leiden University Medical Center
Leiden 2300 RC
The Netherlands
+31 (0)715263121

Wetenschappelijk

P.O. BOX 9600
M.M ter Kuile,
Department of Gynaecology, Leiden University Medical Center
Leiden 2300 RC
The Netherlands
+31 (0)715263121

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	07-08-2018
Aantal proefpersonen:	220
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-04-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55440
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten