A short CBT intervention for sexual rehabilitation among women receiving radiotherapy with gynecological cancer: A pilot study.

Published: 25-07-2013
Last updated: 18-07-2024

To investigate whether a short CBT intervention for sexual rehabilitation is feasible for patients (and their partners) and professionals. The available literature underscores the importance of sexual problems after pelvic RT and the need to develop...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON38516

Source
ToetsingOnline

Brief title
CBT sexual rehabilitation intervention after radiotherapy.

Condition

- Reproductive neoplasms female malignant and unspecified
- 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: CBT intervention, Radiotherapy, Sexual rehabilitation, Vaginal dilation therapy

Outcome measures

Primary outcome

Frequency of dilator use, sexual functioning, sexual distress.

Atrophy, dryness, fibrosis, stenosis and vaginal shortening.

Feasability of vaginal dilation intervention.

Secondary outcome

Fears of sexuality and cancer, vaginal symptoms and self-image, anxiety,

relationship dissatisfaction

Study description

Background summary

Gynaecological cancer treatment, radiotherapy (RT) combined with brachytherapy (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 maintain using vaginal dilators regularly. We developed a short sexual rehabilitation intervention, based on cognitive behavioral therapy (CBT), directed at increasing understanding of both patient (and partner) regarding sexual issues after cancer therapy and benefits of compliance with dilator use.

Study objective

To investigate whether a short CBT intervention for sexual rehabilitation is feasible for patients (and their partners) and professionals.

The available literature underscores the importance of sexual problems after pelvic RT and the need to develop strategies aimed to improve sexual functioning, and thus quality of life, of cancer survivors. As vaginal dilation is an essential component of sexual rehabilitation after pelvic RT, we will focus on acceptance of and compliance with dilator use.

Study design

A prospective uncontrolled multicenter pilot-test of CBT intervention in a sample of at least 1215 patients (and partnersat least 1with a partner, and 2-5 subjects without partner 0 partners) who received pelvic RT for gynaecological cancer. The CBT intervention consists of four sessions of 1 hour, spread over a period of 6 months and one follow-up last session of 30 minutes at 12 months. This pilot study is done using (i) standardized questionnaires on sexual functioning, sexual distress, vaginal symptoms and dilator use, and (ii) standardized physical examination assessing the grade of mucosal changes (atrophy, dryness), fibrosis, signs of vaginal shortening and/or stenosis. Assessment with questionnaires and physical examination will take place before RT (questionnaires on paper) and (online questionnaires) at 1-, 3-, 6, 12, 18 and 24 months follow-up. Filling in the questionnaires at 1, 6, 12 and 24 months after treatment will take 30 to 40 minutes, and before treatment and at 2, 3, 4 and 5 months after treatment 10 minutes maximum. (iii) Semi-structured interviews among the couples and oncology nurses about the overall CBT intervention feasibility will be done at 6 months. Possible partners' presence during the CBT intervention and interview is optional and the patient decides about this. The physical examination will be executed by the patients* own radiation oncologists. The self-report questionnaires and interviews will be delivered by two research assistants (not involved in the CBT treatment). Data will be collected at two university hospitals.

Study burden and risks

Participants get five CBT sessions with material of 30-60 minutes (with possible partner), will have to fill in questionnaires four times (30-40 minutes) and four times four questions (10 minutes maximum), will be interviewed once (30-60 minutes) and will be examined physically during follow-up appointments with their radiotherapist. Partners will be asked to join the CBT sessions and interview, but this is optional. This time investment can be experienced as a burden and participants will be asked about an intimate subject (sexuality and dilation therapy). Participants do not however be in any risk en will be helped with their sexual rehabilitation after radiotherapy.

Contacts

Public
Academisch Medisch Centrum

Postbus 9600 2
Leiden 2300 RC
NL
Scientific
Academisch Medisch Centrum

Postbus 9600 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

In order to be eligible to participate in this study women have to be treated with external beam radiotherapy and brachytherapy for gynaecological cancer at Leiden University Medical Center (LUMC) or Erasmus Medical Center, Rotterdam (EMC), completing their treatment between September 2013 and March 2014. Patients have to be older than 20 years old. Patients with partner must have participated in a sexual relationship for at least 3 months and be sexually active before treatment. We expect that sexual functioning and distress will be affected by the patient*s age. In the scope of this study it will not be attainable to include two homogenous samples of two age groups (20-50 and > 50).

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in this study: insufficient knowledge of the Dutch language or living abroad. In order to offer patients with psychiatric disorders comparable treatment, they will be referred to a senior psychologist or sexologist working at the patient*s own university hospital (at least one available in each centre). Patients* own radiation oncologists will screen potential subjects on the exclusion criteria during the time of diagnosis.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-11-2013
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	25-07-2013
Application type:	First submission
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	NL44759.058.13