Sexual (dys-)function in female childhood cancer survivors

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Objectives1. To assess the prevalence of sexual dysfunction in a Dutch cohort of female childhood cancer survivors.2. To assess the disease-associated risk factors for sexual dysfunction (type of treatment, age at treatment) in female childhood...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Haematopoietic neoplasms (excl leukaemias and lymphomas)
Study type	Observational non invasive

Summary

ID

NL-OMON33449

Source
ToetsingOnline

Brief title
Sexual (dys-) function in female CCS

Condition

- Haematopoietic neoplasms (excl leukaemias and lymphomas)
- Sexual function and fertility disorders

Synonym
sex, sexuality

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: childhood cancer, female, sexual function, survivors

Outcome measures

Primary outcome

Sexual function according tot the Female Sexual Function Index

Secondary outcome

Age at diagnosis of cancer

Type of cancer

Type of treatment

Ovarian function

Study description

Background summary

Since advances in treatment increased survival rates of children with cancer, more attention is drawn to long term effects of treatment and quality of life after cancer. Sexuality is an important determinant of experienced quality of life. Cancer and its treatment can cause damage to one of the physiological systems required for a normal sexual response including hormonal, vascular neurological and psychological elements of sexual function.1 In addition treatment of cancer during childhood and adolescence may put the patient at risk for an impaired psychosexual development with a negative impact on issues needed for a normal sexual function like self-image, sexual identity and psychosocial competences. Studies assessing sexuality in adult childhood cancer survivors are scarce in men but even more so in women. One study among 31 Finnish female childhood leukemia survivors found that sexual behaviour of the surviving women did not differ from apparent sexual functioning of the controls. Their inner sexuality however was more restrictive and less positive.2 Van Dijk et al. described a subjective limitation in sexual life due to the illness in 20% of 60 Dutch childhood cancer survivors of both sexes. Treatment in adolescence was a risk factor for a delay in psychosexual development. 3 In a survey among 217 American young cancer survivors 57% indicated that they had a desire for counseling related to sexuality or intimacy. In 82% this need was not met during treatment and afterwards.4 These

data highlight the need to study sexuality in a large cohort of (female) childhood cancer survivors in order to gain more insight into the extend of the problem and the effects of different types of treatment and different ages of treatment on sexual function. With this information proper counseling and secondary prevention can be offered to future patients and survivors.
References
1. Schover RS. Sexuality and fertility after cancer. Hematology Am Soc Hematol Educ Program 2005:523-7.
2. Puukko L, Hirvonen E, Aalberg V et al. Sexuality of young women surviving leukaemia. Arch Dis Child 1997;76:197-202.
3. Van Dijk EM, van Dulmen-den Broeder E, Kaspers GJL et al. Psychosexual functioning of childhood cancer survivors. Psycho-oncology 2007.
4. Zebrack B. Information and service needs for young adult cancer patients. Support Care Cancer 2008;16:1353-1360.

Study objective

Objectives
1. To assess the prevalence of sexual dysfunction in a Dutch cohort of female childhood cancer survivors.
2. To assess the disease-associated risk factors for sexual dysfunction (type of treatment, age at treatment) in female childhood cancer survivors.

Study design

Methods
Study groups:
- Survivor group
All female 5-year survivors of childhood cancer above the age of 18 years treated in the University Medical Center St. Radboud Nijmegen, the Netherlands, between 1965 and 2003 and who participate in VEVO, a study of fertility and endocrine function among Dutch female childhood cancer survivors (n= about 250).
- Control group
An age-matched control group of female siblings of the survivors.
Exclusion criteria:
- Being unable to read and write
- Not being familiar with the Dutch language
- Mental retardation
For the VEVO-study female survivors and their female siblings are asked to fill in a questionnaire and to visit the hospital for a physical examination and a blood sample. We will ask these women for this research project to fill in an additional validated questionnaire; the Female Sexual Function Index, assessing the following items: sexual desire, arousal, lubrication, orgasm, satisfaction, relationship and pain or other discomfort during sexual activity. Data concerning type of cancer, treatment and age at diagnosis as well as current

ovarian function will be extracted from the medical records and from the VEVO-database. Sexual function according to the FSFI of the surviving women will be compared with sexual function of the control group and will be related to disease dependent factors.

Study burden and risks

10 minutes to read the information about the study and the informed consent.
10 minutes to fill in the FSFI.

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

Female 5-year survivor of childhood cancer
Age of at least 18 years
Treatment in the UMC St. Radboud between 1965 and 2003
Participation in the VEVO-study

Exclusion criteria

Not being able to read and write
Not being familiar with Dutch language
Not understanding the study because of mental retardation

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-01-2010
Enrollment:	250
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	20-08-2009

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL27557.091.09