

# Fertility and sexuality following cancer

<b>Submission date</b> 20/01/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 25/01/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/02/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Cancer in adolescence and young adulthood is very disruptive to a person's life and may interfere with important life goals such as finding a partner and building a family. There is limited amount of knowledge, however, about how many young persons with cancer have sexual problems (sexual dysfunction) and how much they worry about their ability to have biological children (fertility-related distress). The study aims to test the effect of a web-based intervention (i.e. program) to alleviate fertility-related distress and sexual dysfunction in adolescents and young adults with cancer.

### Who can participate?

Patients diagnosed with lymphoma, testicular cancer, ovarian cancer, breast cancer, cervix cancer and tumors of the central nervous system and aged between 15 and 39 at the time of diagnosis.

### What does the study involve?

The project includes two studies. In the first study, adolescents and young adults diagnosed with cancer are asked to complete questionnaires that measure sexual health and worry about their ability to have children. They are asked to complete this questionnaire one year, three years and five years after diagnosis. In addition, young people from the general population that do not have cancer also answer the same questions so that the answers can be compared. All the young people with cancer that report sexual problems and/or worry about their ability to have biological children one year after diagnosis are then invited to take part in the second study. They are randomly allocated to one of two groups. Those assigned to the "web-based intervention" group are given access to a web-based program. The program includes information on the impact of cancer treatments on fertility and sexuality, and present ways to deal with problems in these areas. The materials that make up the program include informative texts, multimedia (pictures, video vignettes and audios) and interactive online activities as well as a discussion forum and the possibility to pose questions to experts and receive personal feedback. The program aims to affect participants' sense of control over one's life (autonomy), competence on how to deal with difficulties, and relatedness ("I am not alone with these problems"). Participants assigned to the "control group" receive standard care and follow-up. All young people in both groups are then followed up 12 weeks after being assigned to their group, 3 years later and, finally, 5 years later, to assess fertility-related distress, sexual dysfunction and quality of life.

What are the possible benefits and risks of participating?

Benefits not provided at time of registration. There is a risk that questions regarding sexual function and fertility-related distress can evoke thoughts and worry in participants. For those individuals who are randomized to the control arm (standard care) there is also a risk of being disappointed for not being able to participate in the intervention. Those randomized to receive the intervention may benefit if the intervention shows to be effective in improving sexual function and reducing fertility-related distress.

Where is the study run from?

Department of Neurobiology, Care Sciences and Society at Karolinska Institutet (Sweden)

When is the study starting and how long is it expected to run for?

December 2016 to December 2018

Who is funding the study?

1. The Swedish Childhood Cancer Foundation
- 2, The Doctoral School in Health Care Science
- 3, The Cancer Research Foundations of Radiumhemmet
- 4, The Swedish Cancer Society
- 5, The Vårdal Foundation
- 6, The Swedish Research Council for Health, Working Life and Welfare

Who is the main contact?

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## Contact information

### Type(s)

Public

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## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## **Study information**

**Scientific Title**

Fex-Can – interventions to alleviate impact of cancer on fertility and sexuality among adolescents and young adults

**Acronym**

Fex-Can (Fertility and sexuality following cancer)

**Study objectives**

The study aims to test the effect of a web-based intervention to alleviate fertility-related distress and sexual dysfunction in adolescents and young adults with cancer who report distress and dysfunction.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Regional Ethical Review Board in Stockholm, 11/27/2013, 12/29/2014 and 02/12/2015, refs 2013/1746-31/4, 2014/2244-32, 2015/2042-32/4

**Study design**

Randomized controlled trial with two arms

**Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Internet/virtual

## **Study type(s)**

Treatment

## **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

## **Health condition(s) or problem(s) studied**

Adolescents and young adults diagnosed with selected cancers (lymphoma, testicular cancer, ovarian cancer, breast cancer, cervix cancer and CNS tumors).

## **Interventions**

Individuals will be identified through national cancer registers, approached by postal mail one year post-diagnosis and asked to complete standardized questionnaires. Those rating high levels of fertility-related distress and sexual dysfunction will invited to participate in an randomized controlled trial.

Participants are then randomly allocated to one of the following groups:

1. The web-based intervention group which will be given access to a web-based intervention with educational and behavior change content, and include multimedia (pictures, video vignettes and audios), interactive online activities (e.g. self-monitoring) and partial feedback support (discussion forum, tailored feedback from experts)
2. Control group, which will receive standard cancer care and follow-up

## **Intervention Type**

Behavioural

## **Primary outcome measure**

1. Fertility-related distress, measured with the Reproduction Concerns After Cancer (RCAC) scale
2. Sexual function, measured with the PROMIS Sexual Function and Satisfaction Measures (global satisfaction with sex life, interest in sexual activity, lubrication, vaginal discomfort, erectile function, orgasm) and selected items developed for use among cancer populations

The effect of the intervention will be evaluated 12 weeks (T2) and 24 weeks (T3) after randomization (short-term evaluation), and 3 years (T4) and 5 years (T5) after diagnosis (long-term evaluation).

## **Secondary outcome measures**

Health-related quality of life, assessed with the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30)

12 weeks (T2) and 24 weeks (T3) after randomization (short-term evaluation), and 3 years (T4) and 5 Years (T5) after diagnosis (long-term evaluation).

**Overall study start date**

01/12/2016

**Completion date**

31/12/2018

## Eligibility

**Key inclusion criteria**

1. Diagnosed with lymphoma, testicular cancer, ovarian cancer, breast cancer, cervix cancer and tumors of the central nervous system
2. Twelve months post-diagnosis
3. Aged 15 to 39 at diagnosis
4. Rating fertility-related distress or sexual dysfunction

**Participant type(s)**

Patient

**Age group**

Mixed

**Sex**

Both

**Target number of participants**

Approximately 75 persons will be included in each arm (intervention vs. standard care)

**Total final enrolment**

124

**Key exclusion criteria**

Patients who do not understand and speak the Swedish language

**Date of first enrolment**

01/02/2017

**Date of final enrolment**

31/01/2018

## Locations

**Countries of recruitment**

Sweden

**Study participating centre**

Karolinska Institutet

Alfred Nobels Allé 23, 23 300

Huddinge  
Sweden  
SE-141 83

## Sponsor information

### Organisation

Karolinska Institutet

### Sponsor details

Solnavägen 1, Solna  
Stockholm  
Sweden  
171 77  
+46 (0)8524 80000  
info@ki.se

### Sponsor type

University/education

### Website

<http://ki.se/en/startpage>

### ROR

<https://ror.org/04hmgwg30>

## Funder(s)

### Funder type

Charity

### Funder Name

Barncancerfonden

### Alternative Name(s)

Swedish Childhood Cancer Foundation

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Trusts, charities, foundations (both public and private)

### Location

Sweden

**Funder Name**

The Doctoral School in Health Care Science

**Funder Name**

Radiumhemmets Forskningsfonder

**Alternative Name(s)**

Cancer Research Foundations of Radiumhemmet

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

Sweden

**Funder Name**

Cancerfonden

**Alternative Name(s)**

Swedish Cancer Society

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

Sweden

**Funder Name**

Vårdalstiftelsen

**Alternative Name(s)**

Vårdal Foundation, Foundation for Health and Allergy Research, Swedish Foundation for Health Care Sciences and Allergy Research

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

Sweden

**Funder Name**

Forskningsrådet om Hälsa, Arbetsliv och Välfärd

**Alternative Name(s)**

Swedish Research Council for Health, Working Life and Welfare, FORTE

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

Sweden

## Results and Publications

**Publication and dissemination plan**

Short-term evaluation is planned to be published during 2018

**Intention to publish date**

30/06/2018

**Individual participant data (IPD) sharing plan**

Not provided at time of registration

**IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other publications</a>	Web-Based Intervention Development	12/04/2016		Yes	No
<a href="#">Results article</a>	Results	29/03/2022	30/03/2022	Yes	No
<a href="#">Protocol article</a>		11/04/2019	17/08/2022	Yes	No



[Other  
publications](#)

18/07 /2017	28/02 /2024	Yes	No
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[Other  
publications](#)

qualitative thematic analysis "What do young adults  
communicate?"

04/07 /2023	28/02 /2024	Yes	No
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