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Fertility and sexuality following cancer

Submission date 20/01/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/01/2016	**Overall study status** Completed	
Last Edited 28/02/2024	**Condition category** Cancer	

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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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 evaluted 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
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Sponsor information

Organisation
Karolinska Institutet

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Solnavägen 1, Solna
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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?
Other publications	Web-Based Intervention Development	12/04/2016		Yes	No
Results article	Results	29/03/2022	30/03/2022	Yes	No
Protocol article		11/04/2019	17/08/2022	Yes	No

Other publications		18/07/2017	28/02/2024	Yes	No
Other publications	qualitative thematic analysis "What do young adults communicate?"	04/07/2023	28/02/2024	Yes	No