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The Fex-Can Childhood project - an observational study and a randomized controlled trial focusing on sexual dysfunction and fertility-related distress in young adult survivors of childhood cancer

Submission date
22/10/2019

Recruitment status
No longer recruiting

Registration date
27/11/2019

Overall study status
Completed

Last Edited
17/04/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Previous research has reported that young adults treated for cancer during their childhood or adolescence are at risk of late effects including sexual problems and impaired fertility. Firm knowledge about how common these problems are, and what factors cause them is however lacking. Also, there are few interventions to offer to those who experience these issues in the aftermath of childhood cancer. This study aims to increase the knowledge about sexual problems and fertility-related distress in young adult childhood cancer survivors and to evaluate if a web-based intervention can help to reduce such problems in this group.

Who can participate?
People aged 19-40 who were diagnosed with cancer when aged 0-17, including those reporting a high level of sexual dysfunction and/or fertility-related distress (for the second part of the study), and an age-matched comparison group from the general population

What does the study involve?
In the first study the researchers investigate sexual problems and fertility-related distress in a large group of childhood cancer survivors and compare the results with an age-matched comparison group from the general population. The childhood cancer survivors are identified via the National Swedish Childhood Cancer Registry, and survivors who are young adults (19-40 years of age, approximately 4500 individuals) are invited to complete a survey. The survey includes questions regarding sexual problems, fertility-related distress, anxiety and depression, body image, and health-related quality of life. The same survey has been sent to an age-matched comparison group from the general population (about 2000 individuals). Childhood cancer survivors who report high levels of sexual problems and/or fertility-related distress are then invited to the second part of the study to test the effect of a web-based psycho-educational intervention on sexual problems and fertility-related distress. The intervention has been

developed together with a group of young persons with a cancer experience to assure that its content is relevant to this population. To evaluate the effect of the intervention participants are randomly allocated either get access to the web-based intervention for 12 weeks (intervention group), or be on a wait-list (control group). After the end of the intervention, the levels of sexual problems and fertility-related distress are compared between the intervention group and the control group to determine if the intervention had an effect. The participants in the control group get access to the intervention three months after the intervention group has completed it.

What are the possible benefits and risks of participating?
Participating in this study is associated with potential benefits such as taking part in an intervention designed to alleviate sexual problems and fertility-related distress. Potential risks for participants who complete the survey and/or participate in the intervention include experiencing discomfort, or even anxiety, due to the sensitive nature of these issues. Great care has been taken to phrase the written information, the survey questions, and the content of the intervention in a manner that does not evoke unnecessary worry. The researchers also encourage participants to contact the research group if they should experience any discomfort related to their participation in this study.

Where is the study run from?
Karolinska Institutet (Sweden)

When is the study starting and how long is it expected to run for?
January 2019 to November 2020

Who is funding the study?
Swedish Childhood Cancer Foundation and Swedish Research Council

Who is the main contact?
1. Prof. Lena Wettergren
lena.wettergren@ki.se
2. Prof. Claudia Lampic
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Contact information

Type(s)
Scientific

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The Fex-Can Childhood project - an observational study and a randomized controlled trial focusing on sexual dysfunction and fertility-related distress in young adult survivors of childhood cancer

Acronym
Fex-Can Childhood

Study objectives
Fex-Can Childhood RCT: The web-based psycho-educational intervention is more effective than a wait-list condition in terms of reduction of sexual problems and fertility-related distress in young adult childhood cancer survivors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/01/2016, Swedish Ethical Review Authority: Etikprövningsmyndigheten (Box 2110, 750 02 Uppsala, Sweden; Tel: +46 (0)10 475 08 00; Email: registrator@etikprovning.se), Dnr: 2015/1609-31; 2018/2688-32; 2019/01066; 2019/04603

Study design
Fex-Can Childhood OS: population-based cross-sectional design, including an age-matched comparison group.
Fex-Can Childhood RCT: randomized controlled design comparing the effect of the web-based psycho-educational intervention to a wait-list control condition.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Sexual dysfunction and fertility-related distress in young adult (19-40 years of age) survivors of childhood cancer (diagnosis at 0-17 years of age, including all malignant diagnoses and brain tumors)

Interventions
In the first study the researchers will investigate sexual problems and fertility-related distress in a large group of childhood cancer survivors and compare the results with an age-matched comparison group from the general population. The childhood cancer survivors will be identified via the National Swedish Childhood Cancer Registry, and survivors who are young adults (19-40 years of age, approximately 4500 individuals) will be invited to complete a survey. The survey will include questions regarding sexual problems, fertility-related distress, anxiety and depression, body image, and health-related quality of life. The same survey has been sent to an age-matched comparison group from the general population (approximately 2000 individuals). Childhood cancer survivors who report high levels of sexual problems and/or fertility-related distress will thereafter be invited to the second part of the Fex-Can Childhood project.

Fex-Can Childhood RCT: The Fex-Can Intervention is a web-based self-help intervention that comprises two programs targeting sexual dysfunction and fertility-related distress respectively; The Fex-Can Sex and the Fex-Can Fertility. The intervention has been developed together with young adult survivors of cancer as research partners. The intervention has been evaluated as to its feasibility with satisfying results. Both the Fex-Can Sex and the Fex-Can Fertility programs are structured in six modules to be delivered over a period of 12 weeks. The programs consist of texts, video vignettes with young adult survivors of childhood cancer discussing the topics covered, exercises, and an online-moderated discussion forum. Randomization will be conducted to either the intervention group or to a wait-list control-condition with an allocation ratio of 1:1. Participants will be allocated in blocks stratified by sex and diagnosis and randomization will be made separately for the two versions of the intervention (Fex-Can Sex and Fex-Can Fertility).

Evaluation of the effect will be conducted directly after the end of the intervention (primary endpoint), at 3 months after the end of the intervention (short-term follow-up), and at 6 months

after the end of the intervention (long-term follow-up). The control group will get access to the intervention after the short-term follow-up assessment, the long-term follow-up assessment will, therefore, be used to determine sustainment of a potential effect of the intervention by within-group analyses. Additionally, a process evaluation including survey questions and a qualitative interview will be conducted to achieve a deeper understanding of the participants' use of the intervention, and of the role of the program in bringing about a possible change in the selected outcomes.

Intervention Type
Behavioural

Primary outcome measure
Fex-Can Childhood RCT:
1. Sexual function, measured with the Patient-Reported Outcomes Measurement Information System Sexual Function and Satisfaction Measure version 2.0 (SexFS version 2.0), directly after the end of the intervention (primary endpoint), at 3 months after the end of the intervention (short-term follow-up), and at 6 months after end of the intervention (long-term follow-up).
2. Fertility-related distress, assessed with the Reproductive Concerns After Cancer scale (RCAC), directly after the end of the intervention (primary endpoint), at 3 months after the end of the intervention (short-term follow-up), and at 6 months after the end of the intervention (long-term follow-up)

Secondary outcome measures
Fex-Can Childhood RCT:
Measured directly after the end of the intervention (primary endpoint), at 3 months after the end of the intervention (short-term follow-up), and at 6 months after the end of the intervention (long-term follow-up):
1. Body image assessed with the Body Image Scale (BIS)
2. Anxiety and depression assessed with the Hospital Anxiety and Depression scale (HADS)
3. Health-related quality of life measured with the EORTC QLQ-C30 (version 3.0)
4. Self-efficacy related to sexual function and fertility assessed with study-specific questions measuring confidence in one's own ability to handle situations, thoughts and emotions related to sexuality (6 items) and to the threat of infertility (6 items)
5. Perceived level of knowledge about general and cancer-related fertility issues examined by a study-specific questionnaire with 10 items

Overall study start date
01/01/2019

Completion date
30/11/2020

Eligibility

Key inclusion criteria
The following inclusion criteria will be applied for the Fex-Can Childhood OS:

Cancer survivor group:
1. Individuals diagnosed with malignant disease at the age of 0-17 years and registered in the National Quality Registry for Childhood Cancer.
2. Age 19-40 at the time of enrollment in the study and registered as residents in Sweden.

Comparison group:
Age 19-40 at the time of enrollment (matching the age of the cancer group) and registered as residents in Sweden.

The following inclusion criteria will be applied for the Fex-Can RCT:
Participating in the Fex-Can Childhood OS study (cancer survivor group) and reporting a high level of sexual dysfunction and/or fertility-related distress defined as 0.5 SD from the population mean in any of the selected domains in the SexFS version 2.0 and/or a mean score of 4 or more in at least one dimension of the RCAC respectively.

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
Fex-Can Childhood OS: 4500; Fex-Can Childhood RCT: 256.

Key exclusion criteria
The following exclusion criteria will be used for the Fex-Can Childhood OS/RCT:
1. Individuals who are unable to read/write in the Swedish language.
2. Participants who report poor health and/or substantial cognitive impairment that prevent completion of the survey/participation in the intervention.

Date of first enrolment
23/08/2019

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Sweden

Study participating centre
Karolinska Institutet
Department of Women’s and Children’s health, Karolinska Institutet
Tomtebodavägen 18A
Stockholm
Sweden
S-171 77

Sponsor information

Organisation
Karolinska Institutet

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Sponsor type
University/education

Website
https://ki.se/en

ROR
https://ror.org/04hmgwg30

Funder(s)

Funder type
Charity

Funder Name
Radiumhemmets Forskningsfonder (grant number 161272)

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 (CAN 2013/886 and CAN 2016/615)

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
Barncancerfonden (TJ2014-0050, TJ2019-0045, PR2014-0177)

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
Vårdalstiftelsen (2014-0098)

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 (2014-4689)

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

Funder Name
Vetenskapsrådet (2017-01530)

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Funder Name
Karolinska Institutet (2-5586/2017)

Alternative Name(s)
Karolinska Institute, KI

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

Publication and dissemination plan

A study protocol is completed and will be submitted for publication in a peer-review journal. The results from the Fex-Can Childhood project will be communicated to scientific, clinical and patient communities through publications in scientific peer-reviewed open-access journals. The researchers will also communicate the results in presentations at international clinical and scientific conferences. They intend to publish the Fex-Can Childhood OS 01/03/2020 and the Fex-Can Childhood RCT 31/12/2020

Intention to publish date

01/03/2020

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are not expected to be made available due to the ethical review act. However, it will be available from the principal investigators (Lena Wettergren and Claudia Lampic, Email: lena.wettergren@ki.se and claudia.lampic@ki.se) on reasonable request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		10/07/2020	12/05/2021	Yes	No
Results article		08/07/2022	19/07/2022	Yes	No
Results article		07/04/2024	17/04/2024	Yes	No