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Internet-delivered treatment for fertility distress and sex problems following cancer

Submission date
10/12/2024

Recruitment status
Not yet recruiting

Registration date
12/12/2024

Overall study status
Ongoing

Last Edited
11/08/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
About 2,300 young adults (aged 18-39 years) are diagnosed with cancer in Sweden every year. Cancer in young adulthood may interfere with important life goals such as establishing romantic relationships and family building, and many young adults experience significant fertility distress and sexual problems as a result of cancer. There's limited support available for such problems today, and few interventions have targeted the needs of the young adult cancer population. The present study aims to evaluate the efficacy of an internet-delivered intervention aiming to alleviate fertility-related distress and sexual dysfunction among young adults following cancer.

Who can participate?
Young adults (aged 18-39 years) diagnosed with any type of cancer in the past 5 years and experiencing fertility-related distress and sexual dysfunction

What does the study involve?
Participants in the present study will be randomly allocated to one of two groups: an intervention group, which will receive access to the internet-delivered, guided self-help intervention Fex-Can 2.0, or a control group, allocated to standard care. Following randomization, participants allocated to the intervention group will be invited to participate in an individual start-up session with a research team member. During this session, a set of modules from the Fex-Can 2.0 intervention will be recommended based on the individual participant's needs and problems. Subsequently, participants will receive access to their modules and follow their own personal set of modules throughout the intervention program, which is delivered over a period of 12 weeks. Modules included in the Fex-Can 2.0 intervention include educational and behavior change components such as multimedia, interactive components (self-monitoring, quizzes, exercises) and a moderated peer discussion forum. Participants will further receive personalized feedback on completing exercises. Participants allocated to the control group will receive standard care and follow-up. Participants will be requested to respond to questionnaires at baseline (before randomization), at mid-intervention (week 6), directly at the end of the intervention, and 12 weeks later.

What are the possible benefits and risks of participating?
Intervention group participants will receive information, support and strategies to manage

fertility-related distress and sexual problems. If proven to be effective, Fex-Can 2.0 will be of great help for young adult cancer patients, as well as for health care providers, as no such intervention is available in Swedish cancer care today.
There are no medical risks of participating in the study. However, some participants may feel that questions about fertility and sexuality are intimate and sensitive. Further, some participants may be reminded of difficult experiences and/or consequences of cancer and cancer treatment, and may further detect and worry about new problems that haven't thought about previously.

Where is the study run from?
Uppsala University (Sweden)

When is the study starting and how long is it expected to run for?
January 2023 to December 2030

Who is funding the study?
1. Swedish Research Council (dnr: 2022-00832)
2. Forte (dnr: 2019-00838)
3. Swedish Cancer Society (dnr: 222311Pj)
4. Cancer Research Funds of Radiumhemmet (dnr: 161272)

Who is the main contact?
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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
An internet-delivered psychoeducational intervention (Fex-Can 2.0) targeting fertility-related distress and sexual dysfunction in young adults diagnosed with cancer: a randomized controlled trial with an internal pilot phase

Acronym
Fex-Can 2.0

Study objectives
Participation in the intervention is hypothesized to decrease fertility-related distress and sexual dysfunction in comparison to solely receiving standard care.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/05/2023, The Swedish Ethical Review Authority (Etikprövningsmyndigheten Box 2110, Uppsala, 750 02, Sweden; +46 (0)10-475 08 00; registrator@etikprovning.se), ref: 2023-02745-01

Study design
Two-armed randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Efficacy

Participant information sheet
No available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Young adults diagnosed with cancer who experience fertility-related distress and/or sexual dysfunction

Interventions
Participants will be randomly allocated using a computer-generated randomization sequence concealed from the researchers to one of the following groups:
1. Intervention group receiving access to the Fex-Can 2.0 internet-delivered intervention. The intervention is delivered over 12 weeks and consists of modules including educational and behavior change content such as multimedia, interactive online activities and an asynchronous moderated peer discussion forum. Participants will receive a recommended set of modules based on their individual needs and problems as assessed in an individual start-up session with a research team member.
2. Control group receiving standard care and follow-up.

Intervention Type
Behavioural

Primary outcome measure
1. Self-reported fertility-related distress is measured with the Reproductive Concerns After Cancer scale (RCAC), assessed at baseline, directly after the end of the 12 week intervention, and 12 weeks after end of the intervention.
2. Sexual function and satisfaction is measured by the Patient Reported Outcomes Measurement

Information System Sexual Function and Satisfaction (PROMIS SexFS) Brief Sexual Profile, assessed at baseline, directly after the end of the 12 week intervention, and 12 weeks after end of the intervention.

Secondary outcome measures
1. Degree of bother regarding sexual functioning and use of therapeutic aids for sexual activity is assessed with additional items from the PROMIS SexFS measure. Assessed at baseline, directly after the end of the 12-week intervention, and 12 weeks after the end of the intervention.
2. Body image is assessed with the Body Image Scale (BIS). Assessed at baseline, directly after the end of the 12-week intervention, and 12 weeks after the end of the intervention.
3. Health-related quality of life is assessed using the EORTC Quality of Life Core Questionnaire (EORTC QLQ-C30). Assessed at baseline, directly after the end of the 12-week intervention, and 12 weeks after the end of the intervention.
4. Symptoms of anxiety and depression are assessed by the Hospital Anxiety and Depression Scale (HADS). Assessed at baseline, directly after the end of the 12-week intervention, and 12 weeks after the end of the intervention.
5. Self-efficacy related to fertility is assessed with a study-specific questionnaire. Assessed at baseline, directly after the end of the 12-week intervention, and 12 weeks after the end of the intervention.
6. Self-efficacy related to sex life is assessed with a study-specific questionnaire. Assessed at baseline, directly after the end of the 12-week intervention, and 12 weeks after the end of the intervention.
7. Fertility-related knowledge is assessed with a study-specific questionnaire. Assessed at baseline, directly after the end of the 12-week intervention, and 12 weeks after the end of the intervention.
8. Sex-related knowledge is assessed with a study-specific questionnaire. Assessed at baseline, directly after the end of the 12-week intervention, and 12 weeks after the end of the intervention.
9. Satisfaction with basic psychological needs will be assessed as a mediator, using the Need Satisfaction and Frustration Scale (NSFS), adapted to needs regarding fertility and sexuality, respectively. Assessed at baseline, at mid-intervention (week 6), directly after the end of the 12-week intervention, and 12 weeks after the end of the intervention.

Overall study start date
01/01/2023

Completion date
31/12/2030

Eligibility

Key inclusion criteria
1. Diagnosed with cancer within the past 5 years
2. Aged 18-39 years at study entry
3. Experiencing significant fertility-related distress and/or sexual problems
4. Prepared to spend at least 30 minutes per week on the intervention website

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Upper age limit
39 Years

Sex
Both

Target number of participants
252

Key exclusion criteria
1. Inability to communicate in Swedish
2. Suicidality or a significant psychiatric condition

Date of first enrolment
01/10/2025

Date of final enrolment
01/12/2027

Locations

Countries of recruitment
Sweden

Study participating centre
Uppsala University
Department of Public Health and Caring Sciences
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Study participating centre
Umeå University
Department of Psychology
Beteendevetarhuset, Mediagränd 14
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Sponsor type
University/education

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ROR
https://ror.org/048a87296

Funder(s)

Funder type
Research council

Funder Name
Vetenskapsrådet

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

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

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
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

Results and Publications

Publication and dissemination plan
Findings of this trial will be disseminated in the scientific, clinical, general and patient communities via presentations at patient organizations, at conferences and through publications in peer-reviewed journals. Additionally, the results of the study will be disseminated using social media, including Facebook and LinkedIn.

Intention to publish date
31/12/2031

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are not expected to be made available due to the sensitive nature of the data.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		29/04/2025	01/05/2025	Yes	No