

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

<b>Submission date</b> 10/12/2024	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 12/12/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/10/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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?  
1. Lena Wettergren, lena.wettergren@uu.se  
2. Claudia Lampic, claudia.lampic@umu.se

## Contact information

**Type(s)**  
Scientific, Principal investigator

**Contact name**  
Prof Lena Wettergren

**ORCID ID**  
<https://orcid.org/0000-0003-1279-2191>

**Contact details**  
BMC, Husargatan 3  
Uppsala  
Sweden  
751 22  
+46 (0)18-471 66 16  
lena.wettergren@uu.se

**Type(s)**  
Scientific, Principal investigator

**Contact name**  
Prof Claudia Lampic

**ORCID ID**  
<https://orcid.org/0000-0002-1739-4486>

**Contact details**

Mediagränd 14  
Umeå  
Sweden  
901 87  
+46 (0)90-786 57 06  
claudia.lampic@umu.se

**Type(s)**

Public

**Contact name**

Miss Johanna Rose

**Contact details**

BMC, Husargatan 3  
Uppsala  
Sweden  
751 22  
+46 (0)18-471 66 01  
fexcan@uu.se

## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

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](mailto:registrator@etikprovning.se)), ref: 2023-02745-01

**Study design**

Two-armed randomized controlled trial

**Primary study design**

Interventional

**Study type(s)**

Efficacy

**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(s)**

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.

**Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

39 years

**Sex**

All

**Key exclusion criteria**

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

**Date of first enrolment**

14/11/2025

**Date of final enrolment**

01/12/2027

## Locations

**Countries of recruitment**

Sweden

**Study participating centre****Uppsala University**

Department of Public Health and Caring Sciences

BMC, Husargatan 3

Uppsala

Sweden

751 22

**Study participating centre****Umeå University**

Department of Psychology

Beteendevetarhuset, Mediagränd 14

Umeå

Sweden

901 87

## Sponsor information

**Organisation**

Uppsala University

**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, Forskningsrådet om Hälsa, Arbetsliv och Välfärd, 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

**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?
<a href="#">Protocol article</a>		29/04/2025	01/05/2025	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes