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A digital support program to improve sexual health after pelvic cancer treatment

Submission date	Recruitment status	[_] Prospectively registered
27/03/2026	Recruiting	[_] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
26/05/2026	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
26/05/2026	Urological and Genital Diseases	[X] Record updated in last year

Plain English summary of protocol
Plain English summary of protocol not provided at time of registration

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Scientific, Public

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Study information

Scientific Title
A digital psychosocial intervention for sexual health after pelvic cancer: A randomized controlled trial

Study objectives
Primary objective
To test whether the digital psychosocial intervention is superior to an active control program in improving sexual health outcomes (assessed with the questionnaire EORTC SHQ22) among individuals treated for pelvic cancer, measured at 2 months (post intervention) after baseline.

Secondary objectives
2. To evaluate the effects of the intervention on patientreported outcomes, including quality of life (EORTC QLQC30), sexual function (PROMIS SexFS v2.0), depressive symptoms (PHQ9), anxiety symptoms (GAD7), and selfefficacy (SEMCDSwe) at 2 and 6 months.
3. To examine adherence patterns to both the intervention and active control programs.
4. To assess participant satisfaction both the intervention and active control programs.
5. To explore sustained effects of the intervention at 6month followup.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/02/2026, Swedish Ethical Review Authority (Etikprövningsmyndigheten Box 2110, Uppsala, 75002, Sweden; +46 0104750800; registrator@etikprovning.se), ref: 2025-08917-02

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Supportive care

Study type(s)

Health condition(s) or problem(s) studied
Sexual health problems and reduced sexual wellbeing following treatment for pelvic cancers (prostate, gynaecological, colorectal, and urinary bladder cancer).

Interventions
Participants will be randomly assigned to either the intervention or control group with a 1:1 ratio. Stratified randomization will be used; the number of stratification variables will be kept to different cancer types included (colorectal, prostate, gynecological and bladder cancer). A blocked randomization list with four participants per block (1 list per strata) will be generated online using the platform Sealed Envelope Ltd. (https://www.sealedenvelope.com/simple-randomiser/v1/lists) by an external researcher. The platform also generates a unique randomization code.

Intervention group:
An 8week digital rehabilitation program delivered on the 1177 "Stöd och behandling" platform. It includes 7 weekly modules with psychoeducation, behavioural exercises, communication and intimacy training, pelvic floor exercises, and genderspecific content. Each module takes ~60 minutes to complete.
Control group:
A shorter digital psychoeducational program containing 4 modules delivered every two weeks over 8 weeks. Content overlaps with the intervention but excludes interactive exercises and skillsbased activities.
Methodology:
Participants complete assessments at baseline, 2 months, and 6 months. The intervention and control programs are accessed remotely. Adherence is tracked via module usage. Concomitant care is allowed.

Intervention Type
Behavioural

Primary outcome(s)
1. Sexual health – sexual satisfaction measured using the EORTC SHQ22 questionnaire, including two multiitem scales (sexual satisfaction, sexual pain) and single items covering treatmentrelated sexual symptoms. Scores range 0–100, where higher scores indicate more symptoms or sexual health problems at baseline (T1), 2 months postbaseline (T2 – primary endpoint) and 6 months postbaseline (T3)

Key secondary outcome(s)
1. Quality of life (global and functional domains) measured using the EORTC QLQC30 v3.0, including global health/QoL, functional scales, and symptom scales. Scores are transformed to 0–100 according to EORTC scoring guidelines at (T1), 2 months postbaseline (T2 – primary endpoint) and 6 months postbaseline (T3)

2. Sexual function measured using the PROMIS Sexual Function (SexFs 2.0). It includes genderspecific domains and general domains of sexual function. Higher scores reflect more of the construct measured (e.g., higher dysfunction or higher function depending on subscale) at baseline (T1), 2 months postbaseline (T2 – primary endpoint) and 6 months postbaseline (T3)

3. Depressive symptoms measured using the PHQ9, a 9item instrument assessing severity of depressive symptoms over the past two weeks. Scores range 0–27, with higher scores indicating greater symptom burden at baseline (T1), 2 months postbaseline (T2 – primary endpoint) and 6 months postbaseline (T3)

4. Anxiety symptoms measured using the GAD7, a 7item scale assessing anxiety symptom severity during the past 14 days. Scores range from 0–21 at baseline (T1), 2 months postbaseline (T2 – primary endpoint) and 6 months postbaseline (T3)

5. Selfefficacy for managing health measured using the SelfEfficacy for Managing Chronic Disease Scale (SEMCDSwe), including six items rated from 1–10; mean total score reflects overall perceived selfefficacy, at baseline (T1), 2 months postbaseline (T2 – primary endpoint) and 6 months postbaseline (T3)

6. Intervention adherence measured using platformrecorded module engagement (number of modules started and completed) and moduleend feedback questions on relevance, workload, and time sufficiency at 2 months postbaseline (T2)

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Treated for one of the following pelvic cancer diagnoses: colorectal, prostate, gynaecological or urinary bladder cancer with either surgery, radiation therapy and chemotherapy or a combination of these treatments.
2. Verbally and verified affected sexual health or function with the questionnaire PROMIS Scale v2.0 – Sexual Function Screener.
3. Possess adequate eHealth literacy assessed with the questionnaire eHEALS at baseline.
4. Possess adequate knowledge of the Swedish language. This will be assessed by adequately filling out the screening questionnaires and responses in a brief assessment interview at inclusion.
5. Verbally reported ambition and time to actively work with the rehabilitation intervention for improvements in sexual health. This will be assessed after a brief walkthrough of the intervention regarding the general premise and approximate time needed to complete (around 60 minutes per module/week).

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
95 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. In, or is planned for, active treatment for cancer with chemotherapy, radiation or surgery is planned.
2. Active cancer treatment start during the trial period is a reason for exclusion.

Date of first enrolment
01/04/2026

Date of final enrolment
01/04/2027

Locations

Countries of recruitment
Sweden

Sponsor information

Organisation
Linnaeus University

ROR
https://ror.org/00j9qag85

Organisation
Länssjukhuset i Kalmar

ROR
https://ror.org/04g3stk86

Organisation
Region Östergötland

ROR

https://ror.org/024emf479

Organisation
Region Jönköpings län

ROR
https://ror.org/01c98q459

Funder(s)

Funder type

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
Crafoordska Stiftelsen

Alternative Name(s)
The Crafoord Foundation

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

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan			30/03/2026	No	No