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Testing a workbook and audio-delivered self-help programme with telephone support from a parent guide for parents of persons treated for cancer during childhood

Submission date
27/02/2026

Recruitment status
Not yet recruiting

Registration date
06/03/2026

Overall study status
Ongoing

Last Edited
06/03/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
A child's cancer diagnosis affects not only the child but the entire family. The child's parents can experience psychological distress long after the child's treatment has ended. Despite this, few parents receive psychological support. This can lead to additional psychological difficulties and costs for the family as well as for society.
Together with parents of persons treated for cancer during childhood, our research team has developed the self-help programme EJDeR. The programme is based on low-intensity cognitive behavioral therapy and is delivered via workbooks, audio files, and video case vignettes, and includes telephone support from a parent guide. The goal of the programme is to improve parents' psychological well-being.
In a previous study, we tested the feasibility of an internet-delivered version of EJDeR. The results showed that parts of the programme’s content, as well as the way it was delivered, should be adapted to better meet parents' needs. Based on these results, we have made adaptations to the programme, e.g., the programme is now delivered via workbooks and audio files rather than the internet. The current version of the programme and planned procedures for a controlled evaluation of the programme are tested in this study.

Who can participate?
Parents of a person diagnosed with cancer at the age of 0–18 years whose treatment was completed 3 months to 5 years earlier, who understand, speak, read, and write Swedish well enough to access the study material, provide informed consent, answer questionnaires, participate in interviews, and work with EJDeR, and who have a mobile phone with a telephone number.

What does the study involve?
If a participant consents to study participation and meets the above criteria for participating, they are randomly allocated to one of two groups. One group gets access to EJDeR and the other group does not get access to EJDeR. Participants who get access to EJDeR work with the

programme for 12 weeks. Everyone who participates in the study can still use the care they already have access to, such as psychological support or prescribed medication via primary care. 12 weeks after being randomly allocated to one of the groups, as well as six months after that, all participants are asked to answer questions via the telephone about their well-being, health, and work life. Participants who get access to EJDeR are asked to participate in an interview about EJDeR 12 weeks after being randomly allocated to EJDeR.

What are the possible benefits and risks of participating?
Being randomly allocated to the group that gets access to EJDeR and working with EJDeR may help participants feel better. Participating in the study involves setting aside time to answer questions. Answering questions about well-being provides all participants with their opportunity to reflect on their well-being, which may be helpful but may also trigger difficult feelings and memories. We are not expecting any serious risks from participating in the study, but if at any time during the study parents report levels of distress that require more intensive support, we direct parents to appropriate mental health services.

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

When is the study starting and how long is it expected to run for?
April 2026 to April 2027

Who is funding the study?
The study is funded by the Swedish Research Council, the Swedish Cancer Society, and the Swedish Childhood Cancer Fund

Who is the main contact?
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Study information

Scientific Title
A workbook and audio-administered, telephone guided, low-intensity cognitive behavioral therapy intervention plus usual care versus usual care alone for improving mental well-being in parents of persons treated for cancer during childhood: pilot randomized controlled trial and embedded mixed methods process evaluation (CHANGE-pilot)

Acronym
CHANGE-pilot

Study objectives
The objectives are to examine the feasibility of:
1. EJDeR delivered via workbooks, audio files, and video vignettes with telephone guidance from a parent guide
2. Planned study procedures for a future evaluation of EJDeR
3. Possible relationships between how EJDeR is delivered, how study participants work with EJDeR, study participants' experience of how EJDeR works, contextual factors, and variation in mental well-being and symptoms of depression, anxiety, and post-traumatic stress (PTSS)

Research questions:

Procedural uncertainties:
1. Is there a difference in sociodemographic characteristics between those invited versus those who consent?
2. What proportion of those invited consent, are assessed for inclusion, are included, and are randomized?
3. What proportion of the intervention and control groups complete questionnaires at baseline, post-treatment, and follow-up?
4. What proportion of responses are missing in each questionnaire for the intervention and control group at baseline, post-treatment, and follow-up?

Intervention uncertainties:
5. What proportion of the intervention group completes the minimum treatment dose?

Methodological uncertainties:
6. What is the variance in mental well-being for the intervention and control groups at post-treatment and follow-up, and is there a correlation with mental well-being at baseline?
7. Is there a difference in mental well-being between the intervention and control groups at post-treatment and follow-up?

Implementation:
8. To what extent do parent guides follow the protocols for EJDeR?
9. To what extent is the intervention group working with EJDeR as intended?

Mechanisms of impact:
10. What potential mechanisms of impact does the intervention group experience with EJDeR, and do they experience a relationship between these and the outcomes of EJDeR?

Context:
11. Are contextual factors related to the intervention group's mental well-being and symptoms at post-treatment? If yes, how?
12. Does the intervention group experience barriers or facilitators when working with EJDeR? If yes, which ones?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 02/02/2026, Swedish Ethical Review Authority (Etikprövningsmyndigheten Box 2110, Uppsala, 750 02, Sweden; +46 (0)10-475 08 00; registrator@etikprovning.se), ref: Dnr 2025-09024-01

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Mental well-being among parents of persons treated for cancer during childhood

Interventions

Inclusion interview:
Potential participants are asked questions via telephone to confirm eligibility. If a person is included, they are asked questions about their sociodemographic characteristics and their child's sociodemographic characteristics and medical data (≈15 minutes).

Baseline assessments:
Clinical outcomes, health economic outcomes, and process outcomes are collected for all participants via telephone (≈30 minutes).

Randomization:
After completing the baseline assessment, participants are randomly allocated to the intervention (EJDeR plus usual care) or control group (usual care alone) in a 1:1 ratio using block randomization (block size of 6). Randomization is conducted through an online software application (https://www.sealedenvelope.com/) by an individual external to the research team.

Intervention content:
EJDeR is a workbook and audio-administered, telephone-guided low-intensity cognitive behavioral therapy (LICBT) intervention tailored to parents of persons treated for cancer during childhood delivered over 12 weeks. Workbooks include text, exercises, illustrations, and written parent case vignettes. Audio recordings of workbook text, including exercise instructions, and videos of parent case vignettes (video case vignettes), are provided via an online platform. The LICBT techniques are worry time and problem-solving. EJDeR is guided by a parent guide with documented advanced CBT skills. Participants randomly assigned to EJDeR can access usual care (see below).

Usual care:
Participants allocated to the control group continue with usual care, which may include (1) psychological support in accordance with national guidelines for treatment of anxiety and depression and (2) prescribed psychotropic drugs via primary care. Participants allocated to the control group will not be offered EJDeR at the end of the trial.

Post-treatment assessments:
Clinical outcomes, health economic outcomes, and process outcomes are collected for all participants via telephone (≈30 minutes) 12 weeks after randomization. The intervention group also answers questions about their experience with EJDeR and the parent guide (≈5 minutes) and participate in a semistructured interview (≈45 minutes).

Follow-up assessments:
Clinical outcomes, health economic outcomes, and process outcomes are collected for all participants via telephone (≈30 minutes) 6 months after post-treatment assessments.

Intervention Type

Behavioural

Primary outcome(s)

1. Mental well-being measured using the Questionnaire on Well-Being (QWB) at baseline, post-treatment (12 weeks after randomization), and follow-up (6 months post-treatment)

Key secondary outcome(s))

1. Symptoms of depression measured using the Patient Health Questionnaire 8-item scale (PHQ-8) at baseline, post-treatment (12 weeks after randomization), and follow-up (6 months post-treatment)

2. Symptoms of anxiety measured using the Generalized Anxiety Disorder 7-item scale (GAD-7) at baseline, post-treatment (12 weeks after randomization), and follow-up (6 months post-treatment)

3. Symptoms of post-traumatic stress measured using the Post-traumatic Stress Disorder Checklist-Civilian version (PCL-C) at baseline, post-treatment (12 weeks after randomization), and follow-up (6 months post-treatment)

4. Health-related quality of life measured using Recovering Quality of Life (ReQoL-10) at baseline, post-treatment (12 weeks after randomization), and follow-up (6 months post-treatment)

5. Health and work life measured using the Resource Use Questionnaire (RUQ) at baseline, post-treatment (12 weeks after randomization), and follow-up (6 months post-treatment)

6. Experience of the content and delivery of EJDeR measured using the Theoretical Framework of Acceptability Questionnaire (TFAQ) at post-treatment (12 weeks after randomization), intervention group only

7. Therapeutic alliance measured using the Working Alliance Inventory – Short Revised (WAI-SR) at post-treatment (12 weeks after randomization), intervention group only

Completion date
26/04/2027

Eligibility

Key inclusion criteria
1. Be a parent of a person diagnosed with cancer at the age of 0–18 years whose treatment was completed 3 months to 5 years earlier
2. Understand, speak, read, and write Swedish well enough to access the study material, provide informed consent, answer questionnaires, participate in interviews, and work with EJDeR
3. Have a mobile phone with a telephone number

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex

All

Total final enrolment
0

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
27/04/2026

Date of final enrolment
27/07/2026

Locations

Countries of recruitment
Sweden

Sponsor information

Organisation
Uppsala University

ROR
https://ror.org/048a87296

Funder(s)

Funder type

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
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
Vetenskapsrådet

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (Zenodo: https://zenodo.org/).

Anonymized quantitative data is deposited in public data repositories (Zenodo). Participants are informed of the data-sharing plans in the participant information sheet and provide informed consent accordingly. Before sharing, all personal identifiers are removed or coded to ensure individual participants cannot be identified. Metadata will be registered in the Swedish National Data Service (SND) catalogue, in accordance with national recommendations from the Swedish Research Council (Vetenskapsrådet), to ensure discoverability through SwePub/SND.

IPD sharing plan summary

Stored in publicly available repository