Plan Overview

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Title: A workbook- and audio-administered, telephone guided, low-intensity cognitive behavioural therapy intervention (EJDeR) for parents of persons treated for cancer during childhood: the CHANGE-pilot randomised controlled trial and an embedded mixed methods process evaluation

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Project abstract:

Introduction Childhood cancer and its treatment place substantial demands on parents, causing significant disruptions in multiple areas of life. Parents report psychological, psychosocial, and economic consequences related to their child's illness. In Sweden, psychosocial support is available to parents via paediatric oncology care during cancer treatment; however, only a minority of parents have access to psychological support after treatment completion. Increasing and improving access to such support could enhance parental mental well-being and help prevent or alleviate negative consequences. One potential solution to provide support is the EJDeR intervention, a co-created workbook- and audio-administered, telephone-guided, low-intensity cognitive behavioural therapy (LICBT) intervention for parents of persons treated for cancer during childhood. Objectives are to examine the feasibility of (1) EJDeR delivered via workbooks, audio files and video case vignettes with telephone guidance from a parent guide, and (2) planned study procedures for a future superiority randomised controlled trial of EJDeR.

Methods and analysis This is a parallel-group, two-arm, pilot randomised controlled trial with a 1:1 allocation ratio. A Parent Advisory Board (PAB) contributes to the research. We aim to recruit 60 parents of persons diagnosed with cancer at age 0–18 years whose treatment was completed 3 months to 5 years earlier. Participants will be randomly allocated to EJDeR plus usual care or usual care alone. EJDeR is delivered over 12 weeks via workbooks, audio files and video case vignettes, with telephone guidance from a parent guide. We will examine feasibility outcomes related to procedural, intervention, and methodological uncertainties using a priori progression criteria following a GO-AMEND-STOP progression framework. We will measure clinical (mental well-being, symptoms of depression, anxiety, and post-traumatic stress) and health economic (health-related quality of life and societal resource use) outcomes at baseline, post-treatment (12 weeks), and follow-up (6 months post-treatment). Data analysis is primarily descriptive.

Ethics and dissemination This trial was approved by the Swedish Ethical Review Authority (Dnr 2025–09024-01, approval date: 2 February 2026). We will obtain written informed consent from all participants and disseminate findings in collaboration with the PAB through peer-reviewed publications, conference presentations, and non-academic dissemination activities such as co-writing plain language summaries and dissemination via childhood cancer organisations.

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A workbook- and audio-administered, telephone guided, low-intensity cognitive behavioural therapy intervention (EJDeR) for parents of persons treated for cancer during childhood: the CHANGE-pilot randomised controlled trial and an embedded mixed methods process evaluation

General Information

Project Title

A workbook- and audio-administered, telephone guided, low-intensity cognitive behavioural therapy intervention (EJDeR) for parents of persons treated for cancer during childhood: the CHANGE-pilot randomised controlled trial and an embedded mixed methods process evaluation

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Description of data – reuse of existing data and/or production of new data

How will data be collected, created or reused?

The following data will be collected from registries:

Information from the Swedish Childhood Cancer Registry about persons treated for cancer during childhood: personal identification number to identify the person’s parents in the Swedish Tax Agency's Population Registry; diagnostic information (age at diagnosis, date of diagnosis, diagnostic group [CSN tumours, Leukaemias, Lymphomas, Solid tumours] and predisposing previous cancer); and treatment dates (end date of primary treatment, end date of relapse treatment, and end date of latest treatment).

Information from the Swedish Tax Agency’s Population Registry. For persons treated for cancer during childhood: personal identification number; reason for deregistration from the registry including date of deregistration; mother’s personal identification number; father’s personal identification number; and guardian’s personal identification number, with date of custody. For parents: personal identification number; reason for deregistration from the registry including date of deregistration; name; public registration address; special mailing address; place of birth, place of birth abroad (if relevant); and country of birth.

All other data will be collected through telephone-administered inclusion interviews, telephone administered questionnaires at baseline, post-treatment (12 weeks) and follow-up (6-months post-treatment) assessments, semi-structured interviews, and intervention session logs. Semi-structured interviews will be audio recorded and transcribed.

No previously collected research data will be re-used for this project.

What types of data will be created and/or collected, in terms of data format and amount/volume of data?

The project will generate multiple types of research data.

Registry data from the Swedish Childhood Cancer Registry consists of CSV-files with the variables mentioned above for approximately 600 persons treated for cancer during childhood.

Registry data from the Swedish Tax Agency's Population Registry consists of CSV-files with the variables mentioned above for up to approximately 1200 parents of persons treated for cancer during childhood.

Personal information containing contact details for consenting participants will be collected on approximately 60 paper consent forms. This data will be entered into Microsoft Excel in accordance with standard operating procedures.

Self-reported sociodemographic data will be collected from approximately 60 telephone-administered inclusion interviews and recorded on paper forms. This data will be entered independently into Microsoft Excel by two research team members in accordance with standard operating procedures.

Quantitative data at baseline will be collected from approximately 60 telephone-administered baseline assessments comprising of six questionnaires per participant and recorded on paper forms. This is equivalent to approximately 360 questionnaires and data will be entered independently into Microsoft Excel by two research team members in accordance with standard operating procedures.

Quantitative data at post-treatment (12 weeks) will be collected from approximately 60 telephone-administered post-treatment assessments comprising of six questionnaires (control group) or eight questionnaires (intervention group) per participant and recorded on paper forms. This is equivalent to approximately 420 questionnaires and data will be entered independently into Microsoft Excel by two research team members in accordance with standard operating procedures.

Intervention implementation and engagement data will be recorded in Parent Guide session logs in individual Word documents for approximately 30 participants.

Intervention delivery data from audio recorded telephone guidance sessions will be collected from approximately 30 participants. This is equivalent to approximately 360 audio recordings (approximately 15–45 minutes each). We aim to analyse 15% of these to examine parent guide fidelity to the EJDeR guidance protocols.

Qualitative data at post-treatment will be collected from approximately 30 semi-structured interviews (30–60 minutes each), generating approximately 30 audio recordings (.wav/.mp4) with corresponding transcripts of all interviews.

Quantitative data at follow-up (6 months post-treatment) will be collected from approximately 60 telephone-administered follow-up assessments comprising of six questionnaires per participant and recorded on paper forms. This is equivalent to approximately 360 questionnaires and data will be entered independently into Microsoft Excel by two research team members in accordance with standard operating procedures.

Data will be stored in the following formats: Microsoft Excel files (.xlsx) and/or SPSS files (.sav) for analysis datasets; plain text files (.txt) and Word documents (.docx) for interview transcripts and project documentation; and audio files (.wav, .mp4) for recorded interviews and telephone guidance sessions.

Overall, the project will generate numeric, textual, and audio data, with total storage requirements remaining modest relative to Uppsala University's secure storage capacity. The total volume of data is expected to remain below 200 GB.

Documentation and data quality

How will the material be documented and described, with associated metadata relating to structure, standards and format for descriptions of the content, collection method, etc.?

The material will be documented with metadata describing its content, structure, source, collection method, date of collection, file format, and any processing or transformation applied. Relevant methodological information, data dictionaries, codebooks, and protocols will be maintained where applicable.

Standardised metadata and established disciplinary standards will be used where relevant to ensure consistency and facilitate interpretation and reuse. File naming conventions, folder structures, versioning, and formats will be documented. Documentation will be maintained throughout the project and updated when changes are made to the data.

How will data quality be safeguarded and documented (for example repeated measurements, validation of data input, etc.)?

Questionnaire data collected via telephone will first be documented on paper and then independently double-entered into separate Excel spreadsheets by two research team members. The files will be compared, discrepancies resolved, and corrections recorded to ensure data accuracy and traceability.

Semi-structured interviews will be audio-recorded and transcribed verbatim manually (i.e., an external transcription company operating under a confidentiality agreement with Uppsala University, ensuring that personal data and other information in the material are protected from unauthorised access). Coding of transcripts will be conducted independently by two research team members, with discrepancies discussed in analysis meetings and refinements documented in the coding framework.

Parent guide session logs will be completed using standardised templates to ensure consistent data capture across participants.

Data quality will be maintained by the PI and the Trial Management Group, which meets regularly to review study procedures. Any issues and decisions will be documented in meeting minutes and relevant project logs.

Storage and backup

How is storage and backup of data and metadata safeguarded during the research process?

Data storage and backup procedures have been developed in consultation with Uppsala University’s IT department, data protection officer, and research data support services. Archiving will be conducted in accordance with Swedish legislation and the EU General Data Protection Regulation (GDPR, EU 2016/679) and in accordance with the approved ethical application and Uppsala University’s archiving regulations.

All digital research data and associated metadata will be stored in Allvis, a web-based platform provided by Uppsala University for storing research data. Data requiring a higher confidentiality level (CIA ≥ 321) will be protected by encryption with VeraCrypt.

Signed consent forms and other paper materials are stored in separate locked fireproof filing cabinets at Uppsala University, accessible only to the research team.

Administrative materials outside the research dataset are stored separately in Argos, Uppsala University's secure shared server.

How is data security and controlled access to data safeguarded, in relation to the handling of sensitive data and personal data, for example?

Data security procedures have been developed in consultation with Uppsala University's IT department, data protection officer, and research data support services, following the Swedish Civil Contingencies Agency's guidelines and the principles of Confidentiality, Integrity, and Availability (CIA). As described above, password protection, VeraCrypt encryption, and locked fireproof cabinets are used depending on the confidentiality level of the data.

Legal and ethical aspects

How is data handling according to legal requirements safeguarded, e.g. in terms of handling of personal data, confidentiality and intellectual property rights?

All personal data will be handled in compliance with GDPR (EU 2016/679) and Swedish legislation, following the same procedures described above.

Registry data from the Swedish Childhood Cancer Registry and the Swedish Tax Agency's Population Registry are used in accordance with the approval from the Swedish Ethical Review Authority (Dnr 2025-09024-01) and the conditions set by the respective registry holders.

Confidentiality is safeguarded through pseudonymisation of all research data and encryption where required. Personal information is stored separately from research data in restricted Allvis areas, with access limited to authorised research team members and permissions controlled by the PI.

How is correct data handling according to ethical aspects safeguarded?

The study has been approved by the Swedish Ethical Review Authority (Dnr 2025-09024-01).

Data will be handled in accordance with applicable ethical guidelines, data protection legislation, e.g., GDPR (EU 2016/679), and the conditions of the relevant ethical approval. Personal and sensitive data will only be collected and processed when necessary for the research purpose and will be minimised where possible.

Access to the data will be restricted to authorised members of the research team, and appropriate technical and organisational measures will be used to protect the data from unauthorised access, loss, or disclosure. Participants' confidentiality will be maintained through pseudonymisation or anonymisation where appropriate. Data will be stored securely, and any sharing or archiving of data will follow the consent provided by participants and applicable ethical and legal requirements.

Oversight is provided by the Trial Management Group, which oversees day-to-day data collection and management, and the Trial Steering Committee, which oversees adherence to the protocol and data analysis plan.

Accessibility and long-term storage

How, when and where will research data or information about data (metadata) be made accessible? Are there any conditions, embargoes and limitations on the access to and reuse of data to be considered?

Metadata about the project and datasets will be recorded in Allvis during the project and registered in the Swedish National Data Service (SND) catalogue in accordance with national recommendations from the Swedish Research Council, ensuring discoverability through SwePub/SND.

Metadata will be made available at the time of publication of research outputs via the SND catalogue and DiVA. In line with open science principles, anonymised quantitative datasets will be deposited in Zenodo together with accompanying metadata, documentation, and a CC BY-NC license, permitting reuse for research and educational purposes while restricting commercial exploitation. All personal information will be removed to ensure that individual participants cannot be identified. Participants are informed of these data-sharing plans in the participant information sheet and provide informed consent accordingly. Qualitative data (audio recordings and interview transcripts) will not be made openly available due to confidentiality requirements and will be archived in accordance with Uppsala University's regulations. Registry data cannot be openly shared and will be retained and destroyed in accordance with conditions stipulated by the respective registry holders.

In what way is long-term storage safeguarded, and by whom? How will the selection of data for long-term storage be made?

During the active project phase, research data are stored in Allvis, a web-based platform provided by Uppsala University for storing research data.

We will store all data, including the code list, for a period of 10 years after the date of the last publication. At this date, a decision will be made by the principal investigator to either continue to store or destroy the data. If there is no longer a need to identify participants, e.g., for data verification purposes, the code list will be destroyed. As the destruction of data is carried out at least 10 years after the date of the last publication, it is not possible to specify in advance exactly how data will be destroyed, however, this will take place in accordance with Uppsala University guidelines on data management, storage, and archiving of data at that time.

Will specific systems, software, source code or other types of services be necessary in order to understand, partake of or use/analyse data in the long term?

Access to Allvis and VeraCrypt is required to access stored data during the project. No other specific systems, software, or source code are necessary.

How will the use of unique and persistent identifiers, such as a Digital Object Identifier (DOI), be safeguarded?

Anonymised quantitative datasets and metadata will be deposited in Zenodo and indexed in the SND catalogue, where a Digital Object Identifier (DOI) will be assigned automatically for long-term referencing. The DOI will ensure that data can be reliably located, cited, and tracked for reuse in future research. The use of persistent identifiers also supports transparent citation, data provenance, and long-term discoverability across international repositories.

Qualitative datasets and other sensitive materials archived internally at Uppsala University will not be assigned persistent identifiers due to confidentiality restrictions.

Responsibility and resources

Who is responsible for data management and (possibly) supports the work with this while the research project is in progress? Who is responsible for data management, ongoing management and long-term storage after the research project has ended?

The principal investigator/project leader will have overall responsibility for data management throughout the research project. The researchers involved in the project will be responsible for following the agreed procedures for data collection, documentation, storage, security, and quality control.

After the project has ended, responsibility for the ongoing management and long-term storage of the research data will be transferred to the appropriate institutional repository or archive in accordance with the organisation's policies and applicable legal and ethical requirements.

What resources (costs, labour input or other) will be required for data management (including storage, back-up, provision of access and processing for long-term storage)? What resources will be needed to ensure that data fulfil the FAIR principles?

Data management will require staff time for data organisation, documentation, quality control, secure storage, backup, and preparation of data and metadata for long-term preservation and sharing. Existing institutional IT infrastructure and approved storage and backup solutions will be used where possible, minimising additional costs.

Additional staff time may be required at the end of the project to prepare the data for archiving, including checking file formats, metadata, documentation, access conditions, and anonymisation where applicable. Institutional research data management, IT, and archive services may be consulted for support.

To support the FAIR principles, staff time is budgeted for double data entry and validation, pseudonymisation, preparation of metadata, indexes, quality control, and preparation of data for repository deposition. Time for data curation, including file cleaning, de-identification checks, versioning, and DOI and metadata entry, is included in the project plan and budget. No other extraordinary costs for long-term storage are anticipated, as Uppsala University provides archiving and preservation infrastructure without additional fees.