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Internet-administered, guided, psychological support (ENGAGE) for parents of children previously treated for cancer

Submission date
29/03/2018

Recruitment status
No longer recruiting

Registration date
19/04/2018

Overall study status
Completed

Last Edited
28/05/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Thanks to medical and technological advancements, most children diagnosed with cancer survive their disease. But, what happens after cancer treatment has finished? The cancer has not only affected the child but the whole family in various ways. For parents, a child's treatment completion is not only an important milestone but also a period of emotional vulnerability. Some parents reports negative long-term emotional consequences years after their child's treatment is completed. In spite of this, there is an unmet need of psychological support in the healthcare sector for those parents experiencing low mood after their child's cancer treatment ended.
A potential solution to address this unmet need is to deliver psychological support via the internet. This may increase access to psychological support and may be an effective and acceptable alternative to standard methods of psychological care.
The goal is to examine the feasibility and acceptability of the internet-administered, cognitive-behavioral therapy based, guided, self-help programme - ENGAGE - for parents of children previously treated for cancer. We will also examine the feasibility and acceptability of the study design to help inform future studies in this area. The study's findings represent a first step to providing parents of children previously treated for cancer with the care that they need.

Who can participate?
Mother and fathers who are feeling distressed or low after their child's completed cancer treatment, to an extent were they feel a need of psychological support. Parents will live in Sweden, and will be able to write and read in Swedish. The child will have been no older than 18 years old when diagnosed with cancer. Parents also need to have access to email, the internet, and a mobile phone and Bank ID to log onto the internet-administered programme.

What does the study involve?
All eligible parents will be offered the opportunity to access the ENGAGE internet-administered programme. ENGAGE is a therapist-guided self-help programme delivered via the internet that was developed in close collaboration with parents. The programme is based on cognitive-behavioral therapy – an evidence based psychological approach. The programme lasts for 10 weeks and parents will receive guidance from an e-therapist on a weekly basis. The programme

starts with one introduction module followed by up to 10 other modules that address specific concerns reported by parents of children previously treated for cancer. Parents will answer questionnaires at three different times: before and after treatment, and at six-months after the treatment has ended.

What are the possible benefits and risks of participating?
We hope that parents who take part in the study will benefit from the ENGAGE programme. Working with the ENGAGE programme may lead to improvements in psychological distress, for example low mood and anxiety. We also hope that participation in the ENGAGE programme and study will not cause any parents harm. When receiving support from an e-therapist, parents may be asked personal questions that they might find difficult to answer, or distressing. The e-therapists are trained to manage distress in a supportive and understanding manner and parents do not need to answer any questions they do not wish to. Parents will also be asked questions about their mood at three different time during the study. Some of these questions will be personal in nature and parents may find them hard to answer, or distressing. Again, parents don' t have to answer these questions if they do not want to. Also, if at any time during the study parents report levels of distress that require more intensive support, we will ensure parents will be referred to more appropriate support for their needs.

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

When is study starting and how long is it expected to run for?
March 2014 to October 2021

Who is funding the study?
1. Vetenskapsrådet (Sweden)
2. Barncancerfonden (Sweden)
3. Cancerfonden (Sweden)

Who is the main contact?
1. Professor Louise von Essen (scientific)
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
A feasibility study of an internet-administered, guided, CBT-based, self-help intervention (ENGAGE) for parents of children previously treated for cancer

Acronym
ENGAGE

Study objectives
The aim is to examine the feasibility and acceptability of the internet-administered, cognitive behavioral therapy (CBT)-based, guided, self-help intervention ENGAGE for parents of children previously treated for cancer and the study procedures for a future controlled trial. The key feasibility outcomes examined via the proposed protocol concern methodological, procedural, and clinical uncertainties, including:
1. Estimates of likely recruitment and retention rates
2. Feasibility and acceptability of data collection instruments and data collection procedures
3. Feasibility and acceptability of the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Ethical Review Board in Uppsala, Sweden has granted approval for the study, 14/03/2018. ref: 2017/527

Study design
The study has an uncontrolled, within-group, baseline, post-treatment (12 weeks), and 6-month follow-up design with an embedded qualitative and quantitative process evaluation

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Posttraumatic stress, depression, anxiety

Interventions
ENGAGE can be described as an internet-administered, guided, cognitive-behavioral therapy (CBT) based, self-help intervention. All participants will receive the intervention. The intervention is guided by an e-therapist for 10 weeks. Guidance will be provide via video or telephone call (initial and mid-treatment support sessions) with additional email support provided each week. The intervention comprises of one introductory chapter followed by up to 10 treatment modules addressing key concerns identified for the population. The intervention is 10 weeks. Participants will be followed-up post-intervention (12 weeks post allocation) and 6 months follow-up.

Intervention Type
Behavioural

Primary outcome measure
Recruitment and eligibility is assessed by:
1. Number of parents identified via the Swedish Childhood Cancer Registry and the Swedish Tax Agency and/or via advertisements at the end of the 6 month recruitment period
2. Percentage of parents assessed for eligibility; fulfilling inclusion criteria, and included (of total number identified) at the end of the 6 month recruitment period
3. Ambiguities regarding eligibility criteria throughout the 6 month recruitment period
4. Reasons for ineligibility throughout the 6 month recruitment period
5. Reasons for non-participation throughout the 6 month recruitment period

Data collection is assessed by:
1. Percentage of participants completing questionnaires at baseline, post-treatment (12 weeks) and 6 month follow-up
2. Numbers of missing items on each clinical outcome measurement at baseline, post-treatment (12 weeks) and 6 month follow-up
3. Types and number of potential uncertainties in diagnostic interviews at baseline

Attrition is assessed by:
1. Rates of study dropout at post-treatment (12 weeks) and 6 month follow-up
2. Rate of intervention dropout at post-treatment (12 weeks)

Resources needed to complete the study and the intervention is assessed by:
Length of time required for:
1. participants to work through the intervention at post-treatment (12 weeks)
2. participants to complete questionnaires and interviews at baseline, post-treatment (12 weeks) and 6 month follow-up
3. e-therapists to deliver the intervention at post-treatment (12 weeks)
4. study personnel to administer the study, assessed at the end of the feasibility trial

Participants' adherence to intervention is assessed by:
Number of:
1. opened introductory chapters at post-treatment (12 weeks)
2. opened CBT modules, completed action plans at post-treatment (12 weeks)
3. completed video or telephone assessment sessions at post-treatment (12 weeks)
4. completed 'booster' support sessions at post-treatment (12 weeks)

Participants' use of the intervention is assessed by:
Number of:
1. logins at post-treatment (12 weeks)
2. use of optional support functions at post-treatment (12 weeks)

E-therapists' adherence to intervention is assessed by:
1. Content of internet-administered written e-therapist-parent communication at post-treatment (12 weeks)

Participants' acceptability of intervention and data
1. Reasons for poor attendance and withdrawal from study and intervention at post-treatment (12 weeks) and 6 month follow-up
2. Impressions and experiences of working with the intervention (including positive and negative consequences) and of completing questionnaires and interviews at post-treatment (12 weeks)

Secondary outcome measures

1. Symptoms of post-traumatic stress (PTSS) is measured using the revised Post traumatic Stress Disorder Checklist for DSM-5 (PCL-5) and DSM-IV (PCL-C) at baseline, weekly, post-treatment (12 weeks) and 6 month follow-up.
2. Symptoms of depression is measured using the Patient Health Questionnaire (PHQ-9) at baseline, post-treatment (12 weeks) and 6 month follow-up.
3.Symptoms of anxiety is measured using GAD-7 at baseline, weekly, post-treatment (12 weeks) and 6 month follow-up.
4. Frequency of parental fear of cancer recurrence and of their child experiencing another serious health condition is measured using 5 item Likert scales developed by the research team and rated from ”very often” to ”not at all” at baseline, post-treatment (12 weeks) and 6 month

follow-up.
5. Psychological inflexibility and experiential avoidance is measured using the Acceptance and Action Questionnaire, 6-items (AAQ-6) at baseline, weekly, post-treatment (12 weeks) and 6 month follow-up.
6. Depressive inactivity is measured using the Behavioural Activation for Depression Scale (BADS) at baseline, weekly, post-treatment (12 weeks) and 6 month follow-up.
7. Symptoms of fatigue is measured using the Fatigue Severity Scale (FSS) at baseline, post-treatment (12 weeks) and 6 month follow-up.
8. Self-compassion is measured using the Self-Compassion Scale-Short form (SCS-SF) at baseline, post-treatment (12 weeks) and 6 month follow-up.
9. Quality of life is measured using the EQ-5D and with a modified short-version of the Trimbos and Institute of Medical Technology Assessment Cost Questionnaire for Psychiatry (TiC-P), assessing direct and indirect medical costs and indirect non-medical costs at baseline, post-treatment (12 weeks) and 6 month follow-up.
10. Psychiatric disorders is measured using the M.I.N.I neuropsychiatric interview at eligibility interview, post-treatment (12 weeks) and 6 month follow-up

Overall study start date
01/03/2014

Completion date
01/10/2021

Eligibility

Key inclusion criteria
Parents/caregivers (adults, both mothers and fathers) will be included according to:
1. Parent of a child diagnosed with cancer when 0-18 years who has completed cancer treatment 3 months to 5 years previously
2. Resides in Sweden
3. Able to read and understand text in Swedish
4. Has access to e-mail, the internet, and a mobile telephone and/or Bank ID
5. Self-reports a need for psychological support related to the child’s cancer disease and treatment

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Total final enrolment
72

Key exclusion criteria
1. Self-reported or clinician-assessed (based on the M.I.N.I neuropsychiatric interview) symptoms of a severe and enduring mental health difficulty
2. Self-reported or clinician-assessed (based on the M.I.N.I neuropsychiatric interview) misuse of alcohol, street drugs, and/or prescription medication
3. Acutely suicidal
4. Currently attending psychological treatment. Those excluded due to a severe and enduring mental health difficulty, substance misuse, and/or acute suicidality will be guided to appropriate healthcare services

Date of first enrolment
02/03/2020

Date of final enrolment
02/09/2020

Locations

Countries of recruitment
Sweden

Study participating centre
Clinical Psychology in Healthcare, Department of Women's and Children's Health, Uppsala University
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Sponsor information

Organisation
Uppsala University

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Sponsor type
University/education

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ROR
https://ror.org/048a87296

Funder(s)

Funder type
Not defined

Funder Name
Vetenskapsrådet

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National 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
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

Results and Publications

Publication and dissemination plan
The ENGAGE protocol is prepared and planned to be submitted to an open access journal in Spring 2018 (June 2018). Results from the ENGAGE study will be submitted to open access journals in the beginning of 2020.
The results we plan to present are:
1. Intervention feasibility results
2. Intervention adherence/internet-administered CBT usage

Intention to publish date
01/01/2022

Individual participant data (IPD) sharing plan
At present, Swedish Universities are working towards the finalisation of mechanisms to share research data in accordance with General Data Protection Regulation (GDPR), as such the exact criterion cannot yet be specified concerning for how long data will be available, exact data sharing mechanisms and how participant consent will be obtained and any additional ethical or legal restrictions. Once data sharing mechanisms have been put in place, in accordance with GDPR, we will be able to provide further details concerning data sharing

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	14/06/2018		Yes	No
Other publications	intervention development	22/07/2021	21/06/2021	Yes	No
Other publications	nested cross-sectional survey	01/04/2022	04/04/2022	Yes	No
Results article		20/11/2022	22/11/2022	Yes	No
Other publications	E-therapists' views qualitative study	05/06/2024	07/06/2024	Yes	No
Other	Engagement				

publications		28/01/2025	31/01/2025	Yes	No
Other publications	Embedded qualitative interview study	16/05/2025	19/05/2025	Yes	No
Other publications	Embedded semi-structured interview study	27/05/2025	28/05/2025	Yes	No