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Cognitive behavioral therapy for psychological distress in young people diagnosed with cancer during adolescence

Submission date
07/08/2017

Recruitment status
No longer recruiting

Registration date
22/08/2017

Overall study status
Completed

Last Edited
21/09/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Young people who are diagnosed with cancer during adolescence may suffer from psychological distress after the end of cancer treatment. Cognitive behavior therapy (CBT) is a talking therapy that is effective for a range of psychological disorders and has been tested for the treatment of depression, anxiety and post-traumatic stress disorder. There are currently few psychological treatments developed specifically to fit the needs of young survivors of cancer and no study has tested individualized CBT specifically tailored to reduce psychological distress in young survivors of cancer diagnosed during adolescence. The aim of this study is therefore to develop and test a CBT-based treatment targeting cancer-related psychological distress experienced by young people who have completed treatment for cancer diagnosed during adolescence.

Who can participate?
Young people aged between 15-25 who have been diagnosed with cancer during adolescence, have completed successful cancer treatment and experience cancer-related suffering

What does the study involve?
Participants are offered up to 15 weekly 45-minute sessions of individual CBT provided by three resident psychologists. Psychological distress is assessed before treatment, at the end of treatment, and at 3 months after the end of treatment.

What are the possible benefits and risks of participating?
By enrolling in this study participants can receive psychological support. There are no anticipated side effects of the treatment. Working with one's mental health problems can involve some distress. Participants who do not experience improvement or who deteriorate during the treatment might have less confidence in psychological treatments in the future. Participants in need of immediate/more intensive/other psychological treatment than can be offered within this study are guided to appropriate healthcare.

Where is the study run from?
Uppsala University Children's Hospital (Sweden)

When is the study starting and how long is it expected to run for?
May 2014 to October 2016

Who is funding the study?
1. Swedish Research Council
2. Swedish Childhood Cancer Foundation
3. Swedish Cancer Society

Who is the main contact?
Prof. Louise von Essen
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Contact information

Type(s)
Scientific

Contact name
Prof Louise von Essen

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
U-CARE: MAYA

Study information

Scientific Title

Development of psychological treatment for cancer-related suffering experienced by young people diagnosed with cancer during adolescence

Study objectives
Since there are no evidence-based interventions for young survivors of cancer during adolescence who experience cancer-related suffering, the purpose of the current study was to develop and preliminary evaluate if individual CBT can reduce distress among these survivors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board in Uppsala, Sweden, 22/12/2014, Dnr: 2014/443

Study design
Single-group non-randomised open trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Cancer-related psychological distress

Interventions
All participants are offered up to 15 weekly 45-minute sessions of individual CBT provided by three resident psychologists under supervision. The CBT interventions are based on a clinical behavior analysis. Psychological distress is assessed before treatment (baseline), at the end of treatment (post-treatment), and 3-months after end of treatment.

Intervention Type
Behavioural

Primary outcome measure
1. Anxiety, assessed with the Beck Anxiety Inventory (BAI) at baseline, post-treatment and at 3 months after end of treatment
2. Depression, assessed with the Montgomery Åsberg Depression Rating Scale Self-assessment (MADRS-S) at baseline, post-treatment and at 3 months after end of treatment

3. Post-traumatic stress symptoms, assessed with the The PTSD Checklist - Civilian (PCL-C) at baseline, post-treatment and at 3 months after end of treatment
4. Worry, assessed with the Penn State Worry Questionnaire (PSWQ) at baseline, post-treatment and at 3 months after end of treatment

Secondary outcome measures
1. Body dissatisfaction, assessed with the Body Image Scale (BIS) at baseline, post-treatment and at 3 months after end of treatment
2. Experiential avoidance, assessed with the Acceptance and Action Questionnaire (AAQ-II) at baseline, post-treatment and at 3 months after end of treatment
3. Fatigue, assessed with the Fatigue Assessment Scale (FAS) at baseline, post-treatment and at 3 months after end of treatment
4. Functional impairment, assessed with the Sheehan Disability Scale (SDS) at baseline, post-treatment and at 3 months after end of treatment
5. Health anxiety, assessed with the Short Health Anxiety Inventory (SHAI) at baseline, post-treatment and at 3 months after end of treatment
6. Somatic symptoms, assessed with the Patient Health Questionnaire-15 (PHQ-15) at baseline, post-treatment and at 3 months after end of treatment
7. Rumination, assessed with the Rumination Scale of the Response Style Questionnaire (RSQ): at baseline, post-treatment and at 3 months after end of treatment
8. The presence of psychiatric disorders, assessed with the Mini-International Neuropsychiatric Interview (M.I.N.I), a structured diagnostic psychiatric interview for DSM-IV and ICD-10, at baseline, post-treatment and at 3 months after end of treatment

Overall study start date
01/05/2014

Completion date
10/10/2016

Eligibility

Key inclusion criteria
1. Aged 15-25 years at study start
2. Diagnosed with cancer when aged 13-18 years
3. Treated at a paediatric oncology unit in Sweden
4. Completed successful cancer treatment
5. Experience cancer-related suffering

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Currently receive psychological treatment
2. Display psychiatric symptoms in immediate need of treatment

Date of first enrolment
27/02/2015

Date of final enrolment
03/11/2015

Locations

Countries of recruitment
Sweden

Study participating centre
Uppsala University Children's Hospital
Akademiska barnsjukhuset, ing. 95 nbv
Uppsala
Sweden
75185

Sponsor information

Organisation
Uppsala University

Sponsor details
Box 256
Uppsala
Sweden
75105

Sponsor type
University/education

Website
www.uu.se

ROR
https://ror.org/048a87296

Funder(s)

Funder type
Government

Funder Name
Vetenskapsrådet

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

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

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

Results and Publications

Publication and dissemination plan
The results from the trial will be published in a doctoral dissertation at Uppsala University and will be submitted for publication in a scientific journal approximately in November 2017.

Intention to publish date
01/11/2017

Individual participant data (IPD) sharing plan
Ethical restrictions prohibit making the dataset publicly available. Data are available on request from the research group Clinical Psychology in Healthcare at the Department of Women's and Children's Health, Uppsala University for researchers who meet the criteria for access to confidential data. Requests should be sent to PI Prof. Louise von Essen (louise-von.essen@kbh.uu.se).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Qualitative feasibility results	17/04/2018	21/09/2023	Yes	No
Protocol file			21/09/2023	No	No