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Cognitive behavior therapy for psychological distress in parents of childhood cancer survivors

Submission date
06/03/2017

Recruitment status
No longer recruiting

Registration date
08/03/2017

Overall study status
Completed

Last Edited
14/05/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Childhood cancer care has improved dramatically over the past 20 years and the overall survival rate for childhood cancer is now approaching 80 %. Advances in treatments have ensured this development and children struck by cancer experience increasing periods of disease-free survival. Although most children diagnosed with cancer survive the disease, challenges remain for these children and their families. A growing body of research has shed light on the long-term physical and psychological consequences of cancer and it has been shown that childhood cancer survivors and their parents are at risk for psychological problems. Cognitive behavior therapy (CBT) is effective for a range of psychological disorders and has been tested for the treatment of depression, anxiety and post-traumatic stress disorder. To date, no study has tested CBT tailored to psychological distress in parents of childhood cancer survivors. The aim of this study is therefore to find out whether individualized face-to-face CBT can reduce distress in parents of children previously treated for cancer.

Who can participate?
Parents of childhood cancer survivors who experience suffering related to their child’s cancer, 3 months to 5 years after the end of the child´s treatment for cancer.

What does the study involve?
Participating parents are offered 10-15 weekly 45-minute sessions of individual CBT. Psychological distress (post-traumatic stress, depression, anxiety) is assessed before treatment, at the end of treatment, and at 3 months follow-up.

What are the possible benefits and risks of participating?
Possible benefits include reductions in distress as similar treatments have been shown to be effective. Regarding possible risks, participants might experience increased distress at the start of the treatment as they may be reminded about distressing events. Participants who do not experience improvement or who deteriorate during the treatment might have less confidence in psychological treatments in the future.

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?
March 2012 to December 2015

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

Who is the main contact?
Dr Martin Cernvall

Contact information

Type(s)
Scientific

Contact name
Dr Martin Cernvall

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Additional identifiers

Protocol serial number
Petra

Study information

Scientific Title
Development and preliminary evaluation of Individualized face-to-face cognitive behavior therapy for psychological distress in parents of childhood cancer survivors

Study objectives
Since there are no evidenced-based interventions for parents of childhood cancer survivors who experience suffering related to their child's illness, the purpose of the current study was to develop and preliminary evaluate if individual CBT can reduce distress among these parents.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Committee of Uppsala, 17/12/2012, Dnr: 2012/440

Study design
Single-group non-randomised open trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Psychological distress (posttraumatic stress, depression, anxiety)

Interventions
Included parents are offered 10-15 weekly 45-minute sessions of individual CBT provided by two resident psychologists under supervision. Psychological distress (post-traumatic stress, depression, anxiety) is assessed before treatment, at the end of treatment, and at 3-months follow-up.

Intervention Type
Behavioural

Primary outcome(s)
1. 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
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. Anxiety, assessed with the Beck Anxiety Inventory (BAI) at baseline, post-treatment and at 3 months after end of treatment

Key secondary outcome(s))
1. Experiential avoidance, assessed with the Acceptance and Action Questionnaire (AAQ-II) at baseline, post-treatment and at 3 months after end of treatment
2. Worry, assessed with the Penn State Worry Questionnaire (PSWQ) at baseline, post-treatment and at 3 months after end of treatment
3. Rumination, assessed with the Rumination Scale of the Response Style Questionnaire (RSQ) at baseline, post-treatment and at 3 months after end of treatment
4. Perceived quality of life, assessed with the Satisfaction with Life Scale (SWLS) at baseline, post-treatment and at 3 months after end of treatment
5. 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

Completion date
04/12/2015

Eligibility

Key inclusion criteria
1. Parents of children who have finished a successful cancer treatment 3 months to 5 years previously
2. Who experience suffering that they relate to the child's disease
3. Swedish speaking
4. Live relatively close to Uppsala, Västerås or Gävle

Participant type(s)
Carer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
15

Key exclusion criteria
1. Suffer from a psychiatric disorder in immediate need of treatment
2. In psychotherapy
3. If they have suicidal ideations

Date of first enrolment
01/02/2013

Date of final enrolment
15/02/2014

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

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
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

Individual participant data (IPD) sharing plan

Ethical restrictions prohibit making the dataset publicly available. The ethical approval obtained ensures use of the dataset to answer the already stipulated research questions and to ensure that the data are processed in accordance with the Swedish Personal Data Act (Swedish: Personuppgiftslagen; 1998:204). Data are available at request from the research group Clinical Psychology in Healthcare at the Department of Public Health Care Sciences, Uppsala University for researchers who meet the criteria for access to confidential data. Requests should be sent to PI Prof. Louise von Essen.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/04/2018	14/05/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes