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Crisis intervention for parents of children with newly diagnosed cancer: implementation and assessment of efficacy

Submission date
08/12/2011

Recruitment status
No longer recruiting

Registration date
12/01/2012

Overall study status
Completed

Last Edited
03/09/2014

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
When a child is diagnosed with cancer, this entails a crisis for the parents, a traumatic situation that can cause both immediate and long-term psychological stress. Therapy programmes offered to parents during the year following the cancer diagnosis may help them to manage the psychological stresses associated with the childs illness and treatment. Our aim is to study whether crisis therapy intervention conducted by experienced professionals can help parents cope with their childs illness, reducing levels of traumatic stress caused by the diagnosis and treatment. We shall also study the possible influence of various socio-demographic factors (parents age, sex, education, childs cancer type) on the findings.

Who can participate?
Parents of a child recently diagnosed with cancer at the childhood cancer centre at Astrid Lindgren Childrens Hospital in Stockholm.

What does the study involve?
Parents are randomly allocated to an intervention group or a control group. At the beginning of the study period, all parents are asked to fill in a questionnaire in order to gauge the levels of distress they may be experiencing in relation to their childs recently diagnosed illness. They will be asked to fill in same questionnaire once the intervention programme is over, to see whether distress levels have changed since the first occasion when distress was assessed. Parents in the intervention group are offered face to face, 90 minute sessions with the intervention staff. Participation begins shortly after the childs diagnosis and the programme will be concluded within 12 months. Parents in the control group will not take part in the study intervention, only in the assessments of distress. For both groups, assessments of distress take place at similar points in time from the childs diagnosis.

What are the possible benefits and risks of participating?
The study focuses on a sensitive period - the first year following a childs cancer so addressing parents thoughts and feelings associated with the experience may be accompanied by discomfort and emotional pain. At the same time, evidence shows that therapy can be helpful

when facing emotional pain and stress, providing parents with support and strength in coping with their childs illness.

Where is the study run from?
Karolinska Institutet (Sweden).

When is study starting and how long is it expected to run for?
The study ran from October 2000 to March 2005.

Who is funding the study?
The study is funded by The Swedish Childhood Cancer Foundation and The Cancer and Traffic Injury Foundation, Sweden.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Crisis intervention for parents of children with newly diagnosed cancer: development, implementation and assessment of efficacy of a model for treatment of distress and traumatic stress symptoms in a randomised controlled trial where post-intervention distress symptom levels of cases are compared with those of controls receiving standard treatment as usual

Study objectives

1. Is participation in the crisis intervention for parents of children with newly diagnosed cancer associated with less severe psychological symptoms measured post-intervention compared to outcomes of controls receiving only treatment as usual (TAU)?
2. Is the decrease in distress/stress greater among parents offered CIP-CC (Crisis Intervention Program for parents with Children with newly diagnosed Cancer) compared to TAU.
3. How do CIP-CC participants experience and evaluate the CIP-CC?

We hypothesised that participants in the intervention would display less severe symptoms post-intervention than parents receiving TAU

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Karolinska Institute Ethics Committee, Stockholm, 21/10/1999, ref: dnr 99-240

Study design
Single-centre randomised clinical open-label trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Post-traumatic stress, anxiety, depression

Interventions
CIP-CC program: manual-guided, structured and time-limited psychological crisis intervention. Duration: 12 months

Control: treatment as usual, consisting of standard routine psychosocial attention of the treatment unit.

Total duration of follow-up: approximately 13 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Illness-specific distress and generic symptoms of anxiety and depression assesed using the standardised 'Parental Psychosocial Distress in Cancer' (PPD-C) - a 125 item self-report instrument
2. Traumatic and post-traumatic stress assessed using the standardised 'Impact of Events Scale - revised' (IES-R) - a 22-item self-report instrument

Assessed at baseline and follow-up.

Key secondary outcome(s))
For intervention participants:
1. The Client Satisfaction Questionnaire (CSQ-8) to assess participants unitary general satisfaction
2. Evaluation of efficacy and feasibility of the CIP-CC program

Completion date
31/03/2005

Eligibility

Key inclusion criteria
1. Parents of a child with a recent primary cancer diagnosis (i.e. newly diagnosed)
2. The child registered at the study treatment center

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Child registered for treatment of a relapse
2. Child suffering from a known 100% fatal malignancy
3. Child in a palliative treatment stage
4. Parent does not speak Swedish

Date of first enrolment
01/10/2000

Date of final enrolment
31/03/2005

Locations

Countries of recruitment
Sweden

Study participating centre
Karolinska Institutet
Stockholm

Sweden
17176

Sponsor information

Organisation
Swedish Childhood Cancer Foundation (Sweden)

ROR
https://ror.org/05072yv34

Funder(s)

Funder type
Government

Funder Name
Swedish Childhood Cancer Foundation (Sweden), ref: PROJ98/006

Funder Name
Swedish Cancer and Traffic Injury Fund (Sweden), ref: C 20002

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes