

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

<b>Submission date</b> 08/12/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/01/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/09/2014	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 child's illness and treatment. Our aim is to study whether crisis therapy intervention conducted by experienced professionals can help parents cope with their child's 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, child's cancer type) on the findings.

### Who can participate?

Parents of a child recently diagnosed with cancer at the childhood cancer centre at Astrid Lindgren Children's 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 child's 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 child's 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 child's diagnosis.

### What are the possible benefits and risks of participating?

The study focuses on a sensitive period - the first year following a child's 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 child's 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?  
Assoc. Professor Krister K Boman  
krister.boman@ki.se

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Krister K Boman

**Contact details**  
Karolinska Institutet  
Department of Womens and Childrens Health  
Childhood Cancer Research Unit  
Astrid Lindgren Childrens Hospital Q6:05  
Stockholm  
Sweden  
17176  
krister.boman@ki.se

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Quality of life

### **Participant information sheet**

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

### **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 measure**

1. Illness-specific distress and generic symptoms of anxiety and depression assessed 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.

**Secondary outcome measures**

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

**Overall study start date**

01/10/2000

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

Approximately 350

**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)

**Sponsor details**

PO box 5408

Stockholm

Sweden

11484

**Sponsor type**

Government

**Website**

<http://www.barncancerfonden.se/>

**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

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration