

# A manualised preventive counselling program for Children Of Somatically Ill Parents (COSIP)

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| <b>Submission date</b><br>18/07/2011   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>13/10/2011 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>04/05/2017       | <b>Condition category</b><br>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

Children of cancer patients are of increased risk developing psychosocial problems. Psychosocial problems can be problems with behaviours and emotions. It is important that help be provided for families in this situation. A preventive counseling programme for these children could be helpful in improving their quality of life and improve their behavior. The aim of this study is to evaluate our intervention in a controlled trail in Hamburg, Berlin and Leipzig (Germany) to see if it can improve the children's quality of life and psychosocial problems.

### Who can participate?

Families who have a parent with cancer and at least one child between 0-21 years old who are seeking support.

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive child-focused preventive counseling programme. This consists of an evaluation of the parents, the child (or children) and a maximum of six individually customised sessions. Further single sessions with one or each child or parents alone or with family, parents and siblings are available. Participants in the second group do not receive the programme. Participants are assessed before and after treatment and are followed up six months after the programme to address their health related quality of life and their behavioural and emotional problems.

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

There are no notable benefits or risks with participating.

### Where is the study run from?

University Medical Centre Hamburg-Eppendorf (Germany)

### When is the study starting and how long is it expected to run for?

December 2009 to March 2012.

### Who is funding the study?

German Cancer Aid (Germany)

Who is the main contact?  
Thomas Krattenmacher  
(t.krattenmacher@uke.de)

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Birgit Möller

**Contact details**  
University Medical Centre Hamburg-Eppendorf  
Centre of Psychosocial Medicine  
Department of Child and Adolescent Psychiatry and Psychotherapy  
Martinistrasse 52  
Hamburg  
Germany  
20246  
-  
b.moeller@uke.uni-hamburg.de

## Additional identifiers

## Study information

**Scientific Title**  
A naturalistic semi-controlled trial of a manualised preventive counselling program for children of parents with cancer

**Acronym**  
COSIP

**Study objectives**  
Evaluation of interventions effectiveness of a manualized child-focused preventive counselling program for children of parents with cancer compared to a naturalistic course of a cohort elsewhere without specific intervention

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Ethics Committee of the Medical Association of Hamburg, 15 October 2009, ref: PV3322

**Primary study design**  
Interventional

**Study design**

Multi-centre naturalistic controlled trial. One group receives intervention, the other not. Randomization of a previous RCT (ISRCTN34770541) had to be stopped.

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Child and adolescent psychotherapy and psychiatry, psycho-oncology

## **Interventions**

A manualised child-focused preventive counselling program consisting of

1. Evaluation of parent(s)
2. Evaluation of child or children
3. A maximum of six individually customised and focused sessions (e.g. further single sessions with one or each child or a parent alone, sessions with family, parents or siblings)
4. All outcomes will be measured before and after treatment, and at 6 month follow up

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

1. Childrens health-related quality of life with Kid-Screen (8-18 years) rated from childrens and parents view
2. Childrens behavioural and emotional problems measured with Strengths and Difficulties Questionnaire (11-18 years) rated from childrens and parents view

## **Key secondary outcome(s)**

1. Parents self-rated anxiety and depression measured with Hospital Anxiety and Depression Scale (HADS)
2. Family Assessment Device (FAD) to measure familial functioning from parents perspective
3. Family Crisis-Oriented Personal Evaluation Scales (F-COPES) to measure familial coping behaviour in crisis situations
4. Freiburg Questionnaire of Coping with Illness (FKV) to measure parental coping with illness
5. Health Survey (SF-8) to measure parental quality of life
6. Connor-Davidson Resilience Scale (CD-Risc) to measure six different resilience factors
7. Kid-Cope (13-18 years) to measure childrens and adolescents cognitive and behavioural coping with parents cancer disease
8. Ad hoc developed intervention program rating scales to evaluate specific intervention contents and satisfaction with intervention; ratings from parents, childrens (over 11 years) and counsellors viewpoint

## **Completion date**

30/03/2012

## **Eligibility**

### **Key inclusion criteria**

1. Wishing/seeking support
2. At least one parent has cancer
3. At least one child between 0-21 years

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Sex**

All

**Key exclusion criteria**

1. Neither parent has cancer (e.g. other chronic diseases)
2. No informed consent for study participation (the program is provided without study participation)
3. At least one parent has psychotic symptoms or a psychotic mental disorder (ICD-10 or DSM-IV)
4. Acute endangerment of child to self or others
5. Insufficient German language abilities
6. Insufficient mobility of ill parent (the program is then offered to other family members)

**Date of first enrolment**

07/12/2009

**Date of final enrolment**

30/03/2012

**Locations****Countries of recruitment**

Germany

**Study participating centre**

University Medical Centre Hamburg-Eppendorf

Hamburg

Germany

20246

**Sponsor information****Organisation**

German Cancer Aid [Deutsche Krebshilfe] (Germany)

**ROR**

<https://ror.org/01wxdd722>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

German Cancer Aid [Deutsche Krebshilfe] (Germany)

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration