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# A manualised preventive counselling program for children of parents with cancer

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 06/12/2009 | Stopped | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 16/12/2009 | Stopped | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 31/05/2011 | Mental and Behavioural Disorders | [ ] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

## Study information

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

**Acronym**

RCT COSIP

## Study objectives
Evaluation of interventions effectiveness compared to waiting list control of a manualised child-focused preventive counselling program for children of parents with cancer.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics Committee of the Medical Association of Hamburg gave approval on October 15, 2009; (ref: PV3322)

## Study design
Single centre randomised waiting list controlled trial

## Primary study design
Interventional

## 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)

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 Child Behaviour Checklist (1,5-5/ 6-18 years) rated from parents view and Youth Self Report (11-18 years) rated from childrens 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. Strengths and Difficulties Questionnaire (SDQ) to measure childrens and adolescents (exposure through childrens self-rating and additionally parents view
7. Connor-Davidson Resilience Scale (CD-Risc) to measure six different resilience factors
8. Kid-Cope (13-18 years) to measure childrens and adolescents cognitive and behavioural coping with parents cancer disease
9. 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
30/03/2011

### Reason abandoned (if study stopped)
Participant recruitment issues

## 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
Other

### 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**
30/03/2011

# Locations

**Countries of recruitment**
Germany

**Study participating centre**
**University Medical Centre Hamburg-Eppendorf**
Hamburg
Germany
20246

# Sponsor information

**Organisation**
German Cancer Aid (Deutsche Krebshilfe e.V.) (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

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|

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|---|---|---|---|---|---|
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |