

A manualised preventive counselling program for children of parents with cancer

Submission date 06/12/2009	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/12/2009	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 31/05/2011	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes