ISRCTN34770541 https://doi.org/10.1186/ISRCTN34770541

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

Study website
http://www.verbund-kinder-krebskranker-eltern.de

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
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 measure
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

Secondary outcome measures
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

Overall study start date
07/12/2009

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

Age group
Other

Sex
Both

Target number of participants
140 families

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)

Sponsor details

Buschstr. 32
Bonn
Germany
53113
+49 (0)228 729900
deutsche@krebshilfe.de

Sponsor type
Charity

Website
http://www.krebshilfe.de

ROR
https://ror.org/01wxdd722

Funder(s)

Funder type
Charity

Funder Name
German Cancer Aid (Deutsche Krebshilfe) (Germany)

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