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

Submission date
18/07/2011

Recruitment status
No longer recruiting

Registration date
13/10/2011

Overall study status
Completed

Last Edited
04/05/2017

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
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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 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

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

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

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)
4. 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 Strengths and Difficulties Questionnaire (11-18 years) rated from childrens and parents 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. 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

Overall study start date
07/12/2009

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

Age group
Child

Sex
Both

Target number of participants
100 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

30/03/2012

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)

Sponsor details
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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