Social network support and cancer

Submission date 13/08/2015	Recruitment status No longer recruiting	Prospectively registered[X] Protocol
Registration date 19/08/2015	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 30/11/2016	Condition category Cancer	Individual participant data

Plain English summary of protocol

Background and study aims

Each year, nearly 3,500 children are faced with the fact that one of their parents has cancer. Because cancer can be a serious disease, and almost always perceived as such, it often causes a dramatic change in the psychological functioning and quality of life of the family as a whole. Parents at this time will often ask for support so that they provide the best care for their children. People close to the affected family (the family's social network) often want to offer support and help in different ways, but they are often unsure of how best to do so. There is very little research on how social networks can be strengthened and what impact their support can make on a family affected by parental cancer. The purpose of the study is to increase knowledge about how a social network can help children that have a parent living with cancer. Questions we want to answer is whether education and information provided to a family's social network can improve the social support offered and how this support can improve the child's quality of life and general health.

Who can participate?

Families where one of the parents has been diagnosed with cancer within the last five years with at least one child aged between 8-18. People in a recruitment family's social network should be at least 18 years old, can be extended family members, friends, neighbors and work colleagues, and should live close to the family.

What does the study involve?

The families taking part in the study are randomly allocated to one of two groups. Those in group 1 (intervention group) are offered the study program. Those in group 2 (control group) are not. The program lasts for three hours and includes an introduction, education about living with cancer as a family and the importance of social network support, and a discussion on individual family's need for social support. Data on, for example, social support, mental health, quality of life are collected from a set of questionnaires completed by healthy parents living with a parent living with cancer, one child (the oldest if under 18) and people in the family social network at the start of the study, three months into the study and finally, six months into the study.

What are the possible benefits and risks of participating? Not provided at time of registration Where is the study run from? Center for Crisis Psychology, Bergen (Norway)

When is the study starting and how long is it expected to run for? August 2013 to August 2016

Who is funding the study? The Research Council of Norway and the Norwegian Directorate of Health

Who is the main contact? Dr May Hauken

Study website http://www.krisepsyk.no/prosjekter/sosial-nettverksstotte-og-kreft

Contact information

Type(s) Scientific

Contact name Dr May Hauken

Contact details Fortunen 7 Bergen Norway No-5013 Bergen

Additional identifiers

EudraCT/CTIS number 2015-003431-35

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 213049/H10

Study information

Scientific Title

A randomized controlled study on optimizing social network support and quality of life to families living with parental cancer through a Psycho-Educational Program for the Social Network

Acronym Cancer-PEPSONE study: Psycho-Educational Program for the SOcial NEtwork

Study objectives

The purpose of the Cancer-PEPSONE study is to expand the base of knowledge and build competence in networks to help children living with parental cancer. The overall aim of the study is to optimize social support from the social network through a psycho-educational intervention. Based on the project's aims and research model, we hypothesize that: 1. A psycho-educational program will improve the provisions of social support to the affected family

Parental psychosocial health and quality of life will increase through social network support
 The children's psychosocial health and quality of life will improve because of more and better social support and increased parental capacity, mental health and quality of life

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Regional Committee of Research and Ethics in Western (REK West) Norway and the Norwegian Social Science Data Services (NSD), 09/10/2013, ref: 2013/1491/REK vest

Study design Single-center randomized controlled intervention study

Primary study design

Interventional

Secondary study design Randomised controlled trial

Study setting(s)

Home

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

We are studying if increased social support can improve quality of life of healthy partners and children living with parental cancer through a psychoeducational program for the family's network.

Interventions

The study has two arms:

1. The intervention arm

A psycho-educational program for the family and their network members in the intervention group. The parents in the intervention families decide who in the family and which network members would participate in the program. The program is conducted in the families' homes, or else where they chose, by one of three experienced clinical psychologists, all of whom used to work with families and children in crisis. It lasts for approximately three hours. The intervention

that contains the following elements:

1.1. Welcome and introduction (10-15 minutes)

1.2. Psycho-education about consequences of living with cancer in the family and the importance of social network support (approximately 1 hour)

1.3. Discussion (approximately 1½ hours): Based on the teaching session, the goal of the discussion is to enhance the family and its network members' understanding of the value of open communication about the family's need for social support and the network members' ability and willingness to give such support

1.4. Summing up and closing (10 minutes)

A detailed procedure for the intervention is developed and reviewed by the intervention psychologists together with the authors, securing that the intervention is performed in the same manner for all families. After the meeting, the psychologists fill out a form with information about how the intervention went according to the protocol, who attended the meeting (roles /relations), the themes discussed, and a short field note to record any observations about the context and impressions arising from the meeting. All participants in the intervention also fill out an evaluation form on how they experienced the psycho-education.

2. The control group

The control-group do not get the intervention, but "treatment as usual". However, of ethical issues they are offered the intervention after 6 months (after they have filled out the final questionnaire).

Intervention Type

Behavioural

Primary outcome measure

1. Healthy parent: Social support, mental health and quality of life

- 2. Children: Mental health and Quality of life
- 3. Network: Social support

Collected via questionnaires at baseline, 3 months and 6 months.

Secondary outcome measures

1. Healthy parent: resilience, parental capacity

2. Network: quality of life, mental health, resilience

Collected via questionnaires at baseline, 3 months and 6 months.

Overall study start date 01/08/2013

Completion date 30/08/2016

Eligibility

Key inclusion criteria

 A healthy parent having a partner or spouse diagnosed with cancer within the last five years
 One child in every family, aged 8-18 years old, living with a parent who has cancer. With multiple children in the family, the oldest child who is willing to participate is recruited
 Network members: The parents in the intervention group ask the number of network members they want to participate in the intervention. The inclusion criteria for these network members are: 3.1. Extended family members, friends, neighbors and work colleagues of the parents

3.2. 18 years or older3.3. Living nearby the family

Participant type(s)

Mixed

Age group

Mixed

Lower age limit

18 Years

Sex Both

Target number of participants

60 healthy parents living with spousal cancer, 60 children living with parental cancer and approximately 200 network members

Key exclusion criteria

1. Healthy parent: not living with the ill parent or the ill parent has died, serious disease themselves

2. Children: below 8 years, not living with ill parent, serious disease themselves

3. Network members: living more than two hours driving from the family

Date of first enrolment

01/01/2014

Date of final enrolment

31/07/2015

Locations

Countries of recruitment Norway

Study participating centre

Center for Crisis Psychology Fortunen 7 N-5013 Bergen Bergen Norway 5013

Sponsor information

Organisation Center for Crisis Psychology

Sponsor details

Fortunen 7 Bergen Norway No-5013 Bergen +47 (0)55 59 61 80 email@krisepsyk.no

Sponsor type Research organisation

Website www.krisepsyk.no

Organisation University of Bergen

Sponsor details Christies gate 13 Bergen Norway No- 5015 Bergen +47 (0)55 58 27 10 post@psyfa.uib.no

Sponsor type University/education

Website http://www.uib.no/psyfa

Organisation Senter for Krisepsykologi

Sponsor details

Sponsor type Not defined

Website http://www.krisepsyk.no/

ROR

https://ror.org/04wb8fh44

Funder(s)

Funder type Research council

Funder Name Norges Forskningsråd

Alternative Name(s) Forskningsrådet, Norwegian Research Council, Research Council of Norway

Funding Body Type Government organisation

Funding Body Subtype National government

Location Norway

Funder Name The Norwegian Directorate of Health

Results and Publications

Publication and dissemination plan

To be confirmed at a later date, but probably publications in 2016 -2017

Intention to publish date 01/06/2017

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?
<u>Protocol article</u>	protocol	30/12/2015		Yes	No

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No