ISRCTN15982171 https://doi.org/10.1186/ISRCTN15982171

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
2. Parental psychosocial health and quality of life will increase through social network support
3. 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
1. A healthy parent having a partner or spouse diagnosed with cancer within the last five years
2. 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
3. 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 older
3.3. 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?
Protocol article	protocol	30/12/2015		Yes	No

Results article	results	01/10/2017	Yes	No