

Training for parents of children with newly diagnosed cancer: a randomised controlled trial

Submission date 30/05/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/05/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/09/2021	Condition category Cancer	<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL929 (NTR953)

Study information

Scientific Title

Training for parents of children with newly diagnosed cancer: a randomised controlled trial

Study objectives

1. A training, for parents of a child with newly diagnosed cancer, will decreasing general distress and parenting stress
2. Identifying predictors of adjustment, such as family functioning, child behaviour and disease severity

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised, active controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Distress, paediatric cancer, parenting stress, psycho-social intervention, training for parents

Interventions

Problem Solving Skills Training for parents based on Problem Solving Therapy is a training program that incorporates cognitive behavioural principles facilitating coping in stressful situations. Parents of paediatric cancer patients in the training group will be offered five face-to-face sessions in which the principles of problem solving will be applied.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

We expect a decrease in the parents' general distress and parenting stress in the intervention group. This will be measured by:

1. The Profile of Mood States, which measures among others depression, tension and fatigue
2. Parenting Stress Index-short form, which measures the level of stress in the parent-child dyad

Measure moments:

T0: approximately five weeks after diagnoses

T1: six months after diagnoses

T2: one year after diagnoses

T3: two year after diagnoses

Secondary outcome measures

We expect a decrease in the problems of child behaviour and an increase in quality of life in the intervention group. This will be measured by:

1. The Impact of Family Scale, which is a measure of the impact of chronic illness on a family
2. The Dutch version of the Child Behaviour Checklist, this is a proxy measure of behavioural and emotional problems in children
3. The Child Health Questionnaire, which is measure of the child's health status

Measure moments:

T0: approximately five weeks after diagnoses

T1: six months after diagnoses

T2: one year after diagnoses

T3: two year after diagnoses

Overall study start date

01/10/2006

Completion date

01/01/2013

Eligibility

Key inclusion criteria

Parents of children with newly diagnosed cancer who can speak, read and write the Dutch language.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

300

Key exclusion criteria

1. Parents of children with newly diagnosed Acute Myeloid Leukaemia (AML)/Non Hodgkin Lymphoma

1. Parents who are not able to speak, read and write the Dutch language

Date of first enrolment

01/10/2006

Date of final enrolment

01/01/2013

Locations

Countries of recruitment

Netherlands

Study participating centre

Erasmus Medical Centre Sophia

Rotterdam

Netherlands

3000 CB

Sponsor information

Organisation

Erasmus Medical Centre (The Netherlands)

Sponsor details

Sophia Children's Hospital

Dr. Molewaterplein 60

Rotterdam

Netherlands

3015 GJ

Sponsor type

Hospital/treatment centre

Website

<http://www.erasmusmc.nl/content/englishindex.htm>

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Health Services Research (ZorgOnderzoek) Erasmus Medical Centre (The Netherlands)

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