ISRCTN24016185 https://doi.org/10.1186/ISRCTN24016185

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

Submission date 30/05/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/05/2007	**Overall study status** Completed	
Last Edited 23/09/2021	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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

Study type(s)
Quality of life

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration