

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

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

**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

## **Primary study design**

Interventional

## **Study design**

Randomised, active controlled, parallel group trial

## **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