

# CHIP-Family intervention for young children with congenital heart disease and their family

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1) The CHIP-Family intervention will result in improved parental mental health and child psychosocial wellbeing (i.e. less behavioral/emotional problems).&nbsp;2) Parents with poor mental health and children with poor psychosocial wellbeing will...

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON20694

### Source

Nationaal Trial Register

### Brief title

CHIP-Family

### Health condition

Congenital Heart Disease Aangeboren Hartafwijkingen

## Sponsors and support

**Primary sponsor:** Erasmus Medical Center, Sophia Children's Hospital

**Source(s) of monetary or material Support:** Fonds NutsOhra

## Intervention

## Outcome measures

### Primary outcome

Child behavioral/emotional problems (CBCL)  
Parental mental health (SCL-90-R)

## **Secondary outcome**

School days sick/absent (Rotterdam Quality of Life interview)  
School functioning (TRF)  
Executive functioning (BRIEF or BRIEF-P)  
Enjoyment in leisure-time physical activity (Adjusted GEQ)  
Quality of life of children and siblings (CHQ-PF50)  
Parental Worry (PSWQ)  
Parenting Stress (NOSIK and DT-P)  
Quality of life of parents (SF-36)  
Family functioning (FAD)  
CHD-related variables: disease-specific knowledge and illness perception (Rotterdam Quality of Life interview), medical consumption  
Social validity (satisfaction and completion of CHIP-Family)

## **Study description**

### **Background summary**

Compared with healthy children, children with congenital heart disease (CHD) are two times more likely to develop psychopathology (16-27% vs. 10%) and intellectual problems (24% vs. 4 % special education). Parental psychosocial functioning is an important mediator for children's psychosocial wellbeing. Unfortunately, parents of CHD-children are also at elevated risk for mental health problems. Crucial, complex milestones in the life of these families are starting kindergarten or starting the first year of primary school. Thus, a family-based psychosocial intervention is needed to prevent or minimize mental health problems and enhance resilience in these phases of starting school.

Therefore, this single-blinded RCT focuses on further developing and testing such a psychosocial intervention for approximately 4 and approximately 6 year old children with CHD starting kindergarten or primary school (first year) and their families: CHIP-Family. The CHIP-Family intervention consists of a one-day group workshop for parents (problem prevention, psychoeducation, parenting skills), plus a parallel one-day group workshop for children with CHD and one 4 to 10 year old sibling (enhancing resilience, sports exercise), and an individual parent booster session ( $\pm$  4 weeks later). CHIP-Family is provided by psychologists, a pediatric cardiologist, and a physiotherapist. Between October 2016 and June 2017, we will include all children who a) underwent an invasive cardiac procedure (catheter intervention, surgery) for CHD in the Erasmus Medical Center and b) are starting kindergarten (in Dutch: groep 1) or attending the first year of primary school (in Dutch: groep 3) at time of first assessment (T1).

Patients will be randomly allocated to a) CHIP-Family or b) care as usual (CAU). All patients will receive adequate medical care (CAU).

## Study objective

- 1) The CHIP-Family intervention will result in improved parental mental health and child psychosocial wellbeing (i.e. less behavioral/emotional problems).
- 2) Parents with poor mental health and children with poor psychosocial wellbeing will benefit most from the CHIP-Family intervention. Furthermore, disease severity will not predict intervention success.

## Study design

T1: baseline assessment (webbased questionnaires), before CHIP-intervention or care as usual

T2: follow-up assessment, 6 months after T1 (webbased questionnaires)

## Intervention

CHIP-Family (Congenital Heart Disease Intervention Program - Family)

The CHIP-Family intervention consists of:

- 1) A one-day group workshop for mothers and fathers (6 hours; problem prevention, psycho-education, parenting skills), given by two clinical psychologists and a pediatric cardiologist. Approximately 4 weeks later there will be an "individual" follow-up session for each parent couple with a clinical psychologist ( $\pm 1,5$  hours). In each group 14 to 16 parents will take part.
- 2) Simultaneously to the parent group workshop, a separate one-day children's workshop (6 hours) to promote emotional resilience and fun in sports. In each group 14 to 16 children plus one 4 to 10 year old sibling or friend per child take part. The children's workshop is given by two psychologists and a physiotherapist.

The control group will receive care as usual, which means they will receive the regular medical care (without additional psychosocial care).

## Contacts

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## Eligibility criteria

### Inclusion criteria

Eligible are all children who

- a) underwent an invasive cardiac procedure (catheter intervention, surgery) for congenital heart disease in the Erasmus Medical Center and
- b) are approximately 4 or approximately 6 years old and are, respectively, starting kindergarten (in Dutch: groep 1) or attending primary school (in Dutch: groep 3).

### Exclusion criteria

- a) Child's mental retardation due to a specified syndrome and
- b) parental inability to read and/or write Dutch.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2016

Enrollment: 146  
Type: Anticipated

## Ethics review

Positive opinion  
Date: 23-08-2016  
Application type: First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 46273  
Bron: ToetsingOnline  
Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
NTR-new	NL5780
NTR-old	NTR6063
CCMO	NL56872.078.16
OMON	NL-OMON46273

## Study results