

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). 2) Parents with poor mental health and children with poor psychosocial wellbeing will...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20694

Bron

Nationaal Trial Register

Verkorte titel

CHIP-Family

Aandoening

Congenital Heart Disease Aangeboren Hartafwijkingen

Ondersteuning

Primaire sponsor: Erasmus Medical Center, Sophia Children's Hospital

Overige ondersteuning: Fonds NutsOhra

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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

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

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2016
Aantal proefpersonen:	146
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	23-08-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46273
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten