The CHIP-Family intervention for young children with congenital heart disease and their family: a randomized controlled trial

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital cardiac disorders
Study type	Interventional

Summary

ID

NL-OMON46273

Source
ToetsingOnline

Brief title
CHIP-Family for children with congenital heart disease and their family

Condition

- Congenital cardiac disorders

Synonym
congenital heart defects, congenital heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: subsidie van Fonds Nuts Ohra

Intervention

Keyword: congenital heart, family, intervention, psychosocial

Outcome measures

Primary outcome

(Please also see METC protocol par. 8, which also includes references)

Main study parameters/endpoints assessed at baseline assessment (T1) and at 6 months follow-up (T2):

- For children: Child behavioral/emotional problems (CBCL)

- For parents: Parental mental health (SCL-90-R)

Secondary outcome

(Please also see METC protocol par. 8, which also includes references)

Secondary study parameters/endpoints, assessed at T1 and T2 (unless otherwise specified):

- For children: school days sick/absent (T2), school/cognitive functioning, executive functioning, pleasure in sports, quality of life

- For parents: parental worry/stress, quality of life

- For siblings: quality of life

- For family: family functioning

- CHD-related: disease-specific knowledge, illness perception, medical consumption

- Social validity (T2; satisfaction regarding CHIP-Family)

Predictor variables, assessed at T1 and T2:

Demographic variables (T1), medical variables (cardiac diagnosis, New Your

Heart Association classification), life events

Study description

Background summary

(Please also see METC protocol par. 1, which also includes references)

Accumulating evidence demonstrates that children with congenital heart disease (CHD) are at increased risk for behavioral, emotional, and cognitive problems in childhood and adulthood. In line with international research, our previous cohort studies have indicated that CHD-children, compared with healthy children, are two times more likely to develop psychopathology (16-27% vs. 10%); this was irrespective of the type of the cardiac defect. Especially internalizing problems (anxiety, depression), problems with social contacts, and reduced quality of life have been reported, which may hamper school functioning. Moreover, neuropsychological problems are well known in these children. Our previous studies have demonstrated intellectual impairments and elevated percentages of patients that attended special education (24% vs. 4 % in norm). This has long-term consequences; a long-term cohort study of our research group has shown that adults with CHD overall had a lower occupational and educational status and lower income compared with the general population. The combination of behavioral/emotional problems, developmental delay, and school difficulties, represents the most common morbidity affecting the quality of life in school-aged survivors of CHD [9]. Furthermore, children with CHD often have reduced stamina and participate less in exercise and sports. This has a negative impact on their quality of life.
Research has shown that parental (especially maternal) factors play a crucial role in children*s psychosocial wellbeing. Maternal mental health and worry have appeared to be more important predictors of children*s psychosocial wellbeing than illness severity. Unfortunately, parents of CHD-children are also at risk for psychosocial problems (1 year prevalence 7-22%; e.g. anxiety, depression). Most studies have documented on psychosocial morbidity in mothers, while fathers have been largely neglected. Clinical experience learns that fathers play a crucial role in family functioning. Since parental psychosocial functioning is an important mediator in children*s wellbeing, a family-based psychosocial intervention is very important to prevent or minimize mental health problems of CHD-children and their parents, and also to strengthen children*s emotional resilience.
For parents and children with CHD, key milestones in life present more barriers

and challenges than for families with healthy children. Such key developmental milestones are: starting kindergarten at 4 and 5 years of age (a major step towards *letting go* for parents and towards autonomy for children) and starting primary school at 6 and 7 years of age (structurally places cognitive demands and pressures on the child). Considering the emotional and cognitive vulnerability of CHD-children in these milestone periods, their reduced exercise capacity, and the need expressed by 40% of parents in our institution for a psychosocial intervention, it is very important to develop a family-centered intervention in which the child and both parents play a central role. Through such an intervention, psychological problems of children with CHD and their parents can be reduced or prevented, and school functioning, emotional resilience, and sport participation of children can be improved. This can improve the quality of life of children and also that of their parents, enabling them to coach their children more adequately. It can also enhance mental and physical health of children with CHD and their siblings, and the participation in social activities. Therefore, this study focuses on further developing and testing such a psychosocial intervention of 4 to 7 year old children with CHD and their families.
Until now, the only published evidence-based intervention tailored to the developmental transition of starting school for young children with CHD, is the Congenital Heart Disease Intervention Program * School (CHIP-School). The CHIP-School study focused on promoting psychosocial wellbeing of preschoolers with CHD and their mothers. Recently, the efficacy of CHIP-School was proven, with significant gains in: maternal mental health, reduced perceived strain on the family, and less days *sick*/less school absence of the child. However, as to child psychosocial wellbeing, only a non-significant, though positive, trend was found.
Shortcomings of CHIP-School were that neither a separate child module to enhance child emotional resilience, nor fathers were included. In collaboration with the CHIP-developer (prof. McCusker, Belfast) we will innovate, strengthen and extend CHIP-School, thus developing a new program: CHIP-Family.
In the new program, CHIP-Family, 1) a tailored child module to further improve children*s wellbeing and 2) fathers (multi-informant approach) will be included. Also, 3) the social validity of CHIP-Family (i.e. how parents evaluate the intervention; satisfaction) and its separate elements will be studied in order to identify the most beneficial ingredients.

Study objective

The objective of this study is to investigate:
1) the effectiveness of CHIP-Family on psychosocial wellbeing (i.e.: behavioral and emotional problems) in 4 to 7 year old children who underwent cardiac surgery or a catheter intrervention for CHD.
2) the effectiveness of CHIP-Family on parental mental health (for both mothers and fathers) of parents of these children.
3) the effectiveness of CHIP-Family on:
- psychosocial wellbeing of the CHD-children, consisting of: school

functioning, sports participation, and quality of life;
- quality of life of their brothers/sisters.
4) which psychosocial and medical factors can predict the success of CHIP-Family.

Study design

(Please also see METC protocol par. 3 and fig. 1)

This is a single-center, single blinded, randomized controlled trial (RCT). The baseline assessment (T1) will take place within 2 months after starting kindergarten or primary school. Families will then be randomly allocated - stratified for age and CHD severity - to the CHIP-Family or the care as usual (CAU) group. All patients will receive adequate medical care. Patients who are randomized to the CHIP-Family group will also complete a social validity assessment within 2 weeks after the intervention. The post-assessment (T2) will take place 6 months after T1.

It was explicitly chosen to do the follow-up assessment 6 months after T1 (instead of direct post-test assessment immediately after CHIP-Family) because:
1) we want to test the effect of CHIP-Family on psychosocial well-being and school functioning over a longer period of time (this has more clinical relevance in our opinion than a direct post-assessment).
2) we want to avoid a *test effect*; if children and parents remember the items of the questionnaires after such a short interval, this will increase the likelihood of a test effect.
3) several questionnaires explicitly ask in their instructions how a child or adult has felt over a longer period of time. Thus, repeating the questionnaires after a too short interval (a direct post-assessment) is not possible without compromising the psychometric basis, and therefore contra-indicated.

Intervention

(Please also see METC protocol par. 5)

The CHIP-Family intervention consists of:
- A one-day (6 hour) group workshop for mothers and fathers (problem prevention, psycho-education, parenting skills), plus for each parent couple an *individual* follow-up session (1 hours, ± 4 weeks later). In each group, 7 to 11 parents take part.
- A separate one-day (6 hours) children's workshop to promote emotional resilience and fun in sports. In each group 7 to 11 children plus one sibling per child take part. The children*s workshop takes place simultaneously with the parent workshop. To keep the size of the children*s group workshop realistically feasible to work with and to have a comparable amount of participating siblings per child, only one sibling per child can participate in

this group workshop.

The new children's module (group workshops and individual follow-up sessions) includes:
- Child-friendly, playful exercises, based on the evidence-based FUN FRIENDS!-protocol. This FUN FRIENDS!-protocol is the only cognitive behavioral therapy protocol for 4- to 7-year-olds in the Netherlands and has been published by the dept. of Child and Adolescent Psychiatry/Psychology of the Erasmus MC.The cognitive behavioral therapy-exercises focus specifically on themes related to CHD, such as: sports and exercise tolerance, relaxation, promoting autonomy, strengthening self-esteem, making friends, problem solving skills and positive thinking.
- Sports exercises, taught by an experienced physiotherapist. The exercises are based on a standardized training program. Previous research of our team has shown that these exercises are effective in improving the quality of life of children with CHD.

CHIP-Family will be performed in a standardized manner by a clinical psychologist (parent workshops/sessions), a pediatric cardiologist (parent workshop), a junior psychologist (child workshops/sessions), and an experienced physiotherapist (child workshops). The junior psychologist will be assisted by master*s students in Psychology (interns). A one-day CHIP-Family training will be given to the psychologists by expert prof. McCusker, developmental psychologist, Queens University Belfast, developer and investigator of the CHIP-protocol.

Care as usual: After randomization, half of the patients will receive the CHIP-Family intervention; the other half will receive their regular medical care, called care as usual (thus no additional psychosocial intervention).

Study burden and risks

The risks associated with participation can be considered negligible and the burden can be considered minimal.

At present, there is no regular psychosocial intervention available for young children with CHD and their families; the majority of families receive no psychosocial care at all. Children with CHD are at increased risk for behavioral, emotional, and cognitive problems in childhood and adulthood. Their parents are also at risk for psychosocial problems. Therefore, psychotherapy will benefit them. Previous research has shown beneficial effects of the CHIP-School intervention. The module added to CHIP-Family are based on the evidence-based FUN FRIENDS!-protocol. Moreover, the added sports exercises have been proven to improve quality of life. Therefore, we hypothesize that the CHIP-Family will result in better child psychosocial wellbeing (i.e. less emotional/behavioral problems) and improved parental mental health.
If patients and their parents do not receive CHIP-Family, but remain in the CAU

group, no harm is done (i.e. compared to the routine treatment which is currently provided). If parents/patients state that they are in need for acute psychosocial care, or if the research psychologist identifies an acute need for psychosocial care, adequate referral will be arranged.

Parents and teachers will be individually asked to report on psychosocial topics via web based questionnaires. This will take approximately 2 hours for parents per assessment, 5 minutes for children and 30 minutes for teachers. Families who are randomly allocated to the CHIP-Family condition, will attend a 6 hour workshop and a parents will attend a 1 hour follow-up session.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Children who underwent at least one invasive cardiac procedure (catheter intervention,

surgery) for CHD in the Erasmus MC and who are approximately 4 to 7 years old at time of the first, i.e. baseline, assessment. All types of congenital heart defects (and a comparable number of kindergarten vs. primary school children) will be included.

Exclusion criteria

a) Child*s mental intellectual impairment (IQ < 70) (due to a specified syndrome) as ascertained by previous standardized assessment or diagnosed by a clinician;
b) parental inability to read/write Dutch;
c) prematurely born children (<37 weeks pregnancy) with only a patent ductus arteriosus and no other CHD.

Study design

Design

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

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-10-2016
Enrollment:	92
Type:	Actual

Ethics review

Approved WMO

Date:	21-09-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	31-10-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20694
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL56872.078.16
OMON	NL-OMON20694