Verbetering van (werk)geheugen, aandacht en concentratie na neonatale IC-opname.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25378

Source
Nationaal Trial Register

Brief title
COGMED na ECMO

Health condition

ECMO (extra corporeal membrane oxygenation); congenital diaphragmatic hernia; working memory; attention; concentration; COGMED training program

Sponsors and support

Primary sponsor: Erasmus MC _ Sophia Children's Hospital
Source(s) of monetary or material Support: Stichting Sophia Kinderziekenhuis Fonds

Intervention

Outcome measures

Primary outcome

z-score of subtest Digit span (compare T1 with T0)

Secondary outcome

-z-score of subtest Digit span (compare T2 with T0)

-z-scores of subtests of neuropsychological assesment (spatial span, 15-word test, Rey Complex Figure Test, Dot Cancellation Test, Trail Making Test, Stroop color-word test, two subtests of BADS-C) (comparison T1 and T2 with T0)

-scores on parent- and teacher-reported questionnaires on executive functioning (BRIEF) and behaviour (SDQ); comparison of T1 and T2 with T0

- scores on parent- and selfreported quality of life (PedsQL and CHQ); comparison of T1 and T2 with T0

-response time and accuracy of the Sternberg item recognition paradigm (SIRP) (compare T1 with T0)
-outcome measure MRI: connectivity strength between the prefrontal and parietal cortex (compare T1 with T0).

Study description

Background summary

Background of the study:

In 2001, we established a unique longitudinal, multidisciplinary follow-up program for neonatal ECMO survivors. To date almost 400 patients aged 0-18 years have been recruited into this program; closely following their medical health and development, including executive functions. Congenital diaphragmatic hernia (CDH) patients form a high-risk subgroup amongst them. Neonatal ECMO survivors and CDH patients (even those without ECMO treatment) generally have normal intelligence but increased risk for learning problems. This affects school functioning and quality of life. Problems with memory, attention, and concentration have been reported and have been shown to increase as children develop ("growing into deficits"). COGMED is an internationally used computer-based cognitive training program that has been shown to improve cognitive performance in children with executive function deficits.

Objective of the study:

• To evaluate short-term (directly after training) and long-term (12 months) effects of cognitive rehabilitation on (working)memory, attention, concentration, and quality of life;

measured by neuropsychological assessments, and reports by parents and teachers

• To evaluate the direct effects of cognitive rehabilitation on brain connectivity; measured by functional MRI (fMRI) during a Sternberg item recognition task (SIRP) working memory task

Study design:

In this single-blind randomized controlled trial we will recruit children from Dutch neonatal ECMO-centers in Rotterdam and Nijmegen. Assessment of children in both study arms will be performed in Rotterdam prior to (T0), directly after (T1) and 12 months after (T2) intervention using neuropsychological tests, standardized questionnaires for parents, teachers and child, and fMRI while performing the SIRP (at T0 and T1 only). Assessment at T0 and COGMED coaching is performed by a psychologist; the researcher who performs the assessments at T1 and T2 will be unaware of treatment allocation (single-blind).

Study population:

Children aged 8 to 12 years with aforementioned diagnoses with an IQ>80, significantly decreased working-memory scores (<-1.5 SD), a sufficient command of Dutch language, and internet access.

Intervention:

The treatment group will undergo COGMED computer training at home and via the Internet 5 days a week during 5 consecutive weeks. The training will be coached by a trained postdoc psychologist.

Primary study parameters/outcome of the study:
Z-score of subtest Digit span determined prior to (T0), directly after (T1) and 12 months after (T2) intervention.

Secundary study parameters/outcome of the study (if applicable):

Z-scores of other neuropsychological tests (working memory, attention, and concentration),

scores on questionnaires (executive functioning, behaviour, and quality of life) at T0, T1, T2. fMRI: connectivity strength between the prefrontal and parietal cortex. For the intervention group: satisfaction

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The intervention does not have direct negative effects; it is an internationally used treatment modality for children. The burden conists of hospital visits (outpatient clinic), 3 times within 12 months. The visits take approximately half a day. For the treatment group the burden also includes 5 weeks, 5 days per week, online training for 45 minutes each day. The treatment group may have direct benefit from the study, the intervention can be offered to controls if proven effective after the end of the study. Being studied with fMRI might cause fear in the children, but they will be prepared carefully including a mock scanning session. In our experience in a study with children of the same age group, fear hardly occurs. If COGMED-training is proven effective, it can be offered to all neonatal ECMO-survivors and CDH patients who show performance problems with working memory, attention and concentration and are therefore at risk for future academic problems.

Study objective

We hypothesize that cognitive rehabilitation using COGMED training improves (working)memory, attention, and concentration in neonatal ECMO survivors and CDH patients aged 8-12 years. Furthermore, we hypothesize that the improvement leads to increased connectivity between (working)memory-related brain structures, including the dorsolateral prefrontal cortex and posterior parietal cortex, measured using functional MRI (fMRI). Finally, we expect that the findings will remain after 12 months following the training.

Study design

pre-intervention assessment (T0), directly after COGMED-training (T1), 12 months after COGMED training (T2)

Intervention

Participants will be allocated to the treatment group or control group. The treatment group will undergo COGMED computer training at home and via the Internet 5 days a week during 5 consecutive weeks.

Contacts

Public

Dept of Pediatric Surgery<br.
Sophia Children's Hospital
Dr Molewaterplein 60
Hanneke IJsselstijn
Rotterdam 3015 GJ
The Netherlands
Scientific
Dept of Pediatric Surgery<br.
Sophia Children's Hospital
Dr Molewaterplein 60
Hanneke IJsselstijn
Rotterdam 3015 GJ
The Netherlands

Eligibility criteria

Inclusion criteria

- Children aged 8 to 12 years who underwent neonatal ECMO-treatment and children with CDH from the Sophia Children’s Hospital and RadboudUMC in Nijmegen

- IQ > 80

- z-score < -1.5 on at least one of the following tests: Digit span (WISC-III-NL), Spatial span of Wechsler Non-Verbal, Rey Auditory Verbal Learning test, and Rey Complex Figure Test.

Exclusion criteria

- syndromes with cerebral developmental delay

- children who use psychopharmaceutical drugs and are unstable (i.e. trial participant or change of dose < 4 weeks prior to the training program)

- insuffcient command of the Dutch language (child and parents) to understand instructions

- no internet access to undergo the COGMED online training program

- for fMRI assessment: anxiety or contraindication for MRI (e.g. pacemaker, permanent braces)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2014
Enrollment:	70
Type:	Actual

Ethics review

Positive opinion

Date:	11-04-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40575
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4448
NTR-old	NTR4571
CCMO	NL47335.078.13
OMON	NL-OMON40575

Study results

Summary results
not available