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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25378

Bron
Nationaal Trial Register

Verkorte titel
COGMED na ECMO

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus MC _ Sophia Children's Hospital
Overige ondersteuning: Stichting Sophia Kinderziekenhuis Fonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2014
Aantal proefpersonen:	70
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	11-04-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40575
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

not available