Improvement of working memory, attention and concentration after neonatal intensive care: a randomized controlled intervention study

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• 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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders congenital
Study type	Interventional

Summary

ID

NL-OMON40575

Source
ToetsingOnline

Brief title
Improvement of working memory after neonatal intensive care.

Condition

- Respiratory disorders congenital
- Cognitive and attention disorders and disturbances
- Vascular therapeutic procedures

Synonym
impaired working memory

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: subsidie Stichting Sophia Wetenschappelijk Onderzoek (Vrienden van Sophia) toegezegd

Intervention

Keyword: cognitive rehabilitation, congenital diaphragmatic hernia, extracorporeal membrane oxygenation, working memory

Outcome measures

Primary outcome

Z-score of subtest Digit span determined prior to (T0), directly after (T1) and

12 months after (T2) intervention.

Secondary outcome

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

Study description

Background summary

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.

Study objective

• 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).

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.

Study burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

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 and z-score is <-1.5 on one or more memory tasks will be eligible for inclusion.

Exclusion criteria

- IQ < 80
- syndromes with cerebral developmental anomalies
- use of psychofarmaceutical drugs while being unstable (i.e. participation in a trial or adjustment of doses < 4 weeks prior to training)
- insufficient command of Dutch language to undergo assessments and/or instructions of COGMED training program
- no internet access
- for MRI: claustrofobia of andere problems such as movement disorders, implants of metal (e.g. pacemaker)

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-09-2014
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	24-02-2014
Application type:	First submission
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: 25378
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL47335.078.13
OMON	NL-OMON25378