Efficacy of the BrainGame Brian training in children born very preterm with attention problems.

Published: 12-10-2015
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Primary objective:investigating whether in a large, representative sample of premature born children (gestational age * 30 weeks and/or birth weight * 1000 gram) with attentional problems in the age of 8 - 12, executing the BrainGame Brian training...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cognitive and attention disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON45165

Source
ToetsingOnline

Brief title
Efficacy of BrainGame Brian training in children born very preterm

Condition

- Cognitive and attention disorders and disturbances

Synonym
executive function disorder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Stichting Kinderpostzegels Nederland;Cornelia Stichting in Beetsterzwaag

Intervention

Keyword: Children, Cognitive, Intervention, Prematurity

Outcome measures

Primary outcome

Primary outcome measure is the score on the Strengths and Weaknesses of ADHD Symptoms and Normal Behavior Rating Scale (SWAN) filled in by parents and teachers.

Secondary outcome

Secondary outcome measures are the scores on several behavioral questionnaires filled in by parents and teachers, performance on several neurocognitive tasks and school performance. See the protocol.

Study description

Background summary

In the Netherlands, every year around 2150 children are born very premature (gestational age * 32 weeks). A large part of these children will encounter behavioral problems and problems at school when they grow up. Deficiencies in complex neurocognitive functions, called executive functions, are thought to be one of the most important undrlieing causes of these problems. Training executive fucntions is a promising new method to reduce the weak performance in school and the behavioral problems in this population. A training that has recently been developed to train executive functions in children, is the digital computer training BrainGame Brian (BGB).

Study objective

Primary objective:
investigating whether in a large, representative sample of premature born children (gestational age * 30 weeks and/or birth weight * 1000 gram) with attentional problems in the age of 8 - 12, executing the BrainGame Brian training leads to a significant decrease in attentional problems.

Secondary objective:
investigating whether the effect of the BrainGame Brian training also generalizes to an improvement in school performance (maths and reading performance).

Study design

The study is a dubbelblind, randomized placebo- and waitlist controlled trial. Children born very preterm that meet the inclusion criteria (parent reported attentional problems) are randomized to three groups: an interventiongroup, a placebogroup and a waitlistgroup. To compare the task and questionnaire outcomes of the very preterm children with attentional problems to those of other children, two reference groups are included: a group of very preterm children without attentional problems and a term control group (both reference groups will not execute the BrainGame Brian training).

Intervention

In the BrainGame Brian training, the executive functions working memory, cognitive flexibility and inhibition are trained. The training is adaptive, which means that the difficulty is adjusted according to the child's performance. The training consists of 25 sessions of approximately 40 minutes each. Children will train during a six-week period for four times a week.

Study burden and risks

The BrainGame Brian training is performed four times a week for a six-week period and is thus quite intensive. Children in the intervention, placebo and waitlistgroup will travel to the AMC for a pre-training measure and two post-training measures at which they perform several neuropsychological tests and parents are asked to fill in several questionnaires. Children in the two reference groups will travel to the AMC/UMC once following the pre-training testprotocol. They will not perform the BrainGame Brian training. The research is not invasive and there are no risks associating with participating in the study. Advantage of participation is a possible improvement of attentional problems in the group of very preterm children that performed the BrainGame Brian training.

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

-parent reported attention problems on the Child Behavior Checklist

Exclusion criteria

-IQ scores < 80 as assessed with short form of the Wechsler Intelligence Scale for Children-III-NL (WISC-III-NL; block design and vocabulary subtests)
-motor of perceptual handicap too profound to allow use of a computer

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-10-2015
Enrollment:	210
Type:	Actual

Ethics review

Approved WMO Date:	12-10-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-08-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-01-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-09-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 27735
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL54163.018.15
OMON	NL-OMON27735