Pilot study on the feasibility of a novel computerized cognitive training program to improve executive function in very preterm children

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

Summary

ID

NL-OMON38940

Source ToetsingOnline

Brief title Feasibility of a cognitive training in very preterm children

Condition

• Cognitive and attention disorders and disturbances

Synonym Executive function disorder

Research involving Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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Source(s) of monetary or material Support: Cornelia Stichting in Beesterzwaag

Intervention

Keyword: Children, Cognitive, Intervention, Prematurity

Outcome measures

Primary outcome

Diverse executive function tests and IQ measurement.

Secondary outcome

not applicable

Study description

Background summary

Despite ongoing improvement in perinatal and neonatal care, developmental outcomes of very preterm birth (gestational age * 30 weeks) remain of significant concern. Although, severe disabilities occur only in approximately 15% of these children, 50-75% of the very preterm children has mild disabilities. Such mild disabilities include lower IQ*s (> 1.0SD below term peers), poor educational achievement, and behavioral problems across childhood. Very preterm children have a 2.7 fold risk for placement in special education, a 14.6 fold risk for grade repetition, and most of them require special educational support at school. Neonatal intervention studies aimed to decrease these adverse late effects of very preterm birth are urgently needed. The nationwide follow-up program of very preterm children stops at the age of 5 years. In the subsequent years, parents often ask for help because of educational and behavioral problems.

Recent studies, including those within our collaboration, have shown that impaired executive function (EF) underlies very preterm children*s scholastic and behavioral difficulties. EF refers to interrelated neurocognitive processes, such as impulse control or working memory, that control thought and behavior. Poor EF after very preterm birth has been related to disruptions of white matter circuits connecting frontal, striatal, and thalamic regions. Remediation of EF skills to delineate the adverse educational and behavioral outcomes of very preterm birth is a novel and promising opportunity for intervention. EFs show a long-term development up to young adulthood and are trainable by adaptive computerized training programs.These studies have presented behavioral and neurophysiological evidence in children with AD(H)D that, for instance, working memory capacity can be enhanced by systematic training and that training effects also yielded significant reduction of attention problems. Positive effects were maintained at 3 months follow-up.

Study objective

This pilot study is set up to test the feasibility of the BrainGame Brian program in a small subsample of very preterm children at 8 to 10 years of age. Evidence that the program is feasible and differences in EF between pre-training assessments and post-training assessments will be used to set up a randomized controlled study.

Study design

Ten very preterm children of the former PINO study, please refer to section 3.1, with scores in the (sub)clinical range, i.e. T > 60, on the Behavior Rating Inventory for Executive Function (BRIEF) and whose parents gave permission to be approached for participation in future studies will be invited. An information letter about the study and an informed consent form will be sent to parents with a request to participate. If parents want to participate with their child they are asked to return the informed consent form signed by both parents. If parents do not reply within two weeks then the researcher will friendly inquire about their participation by telephone. After return of the informed consent form, parents and children will be phoned to make the first appointment. During this appointment, a short IQ examination to derive an estimation of the child*s baseline level of cognitive functioning and a couple of EF tests will be administered to the child. In addition, the researcher will explain all aspects of the training to parents and child. The the training phase starts. For the first training session the researcher will visit parents and the child at home and help them to get started. After 10 and 20 training sessions, the researcher will plan a home visit to get informed whether parents and child are successfully involved in the training and to answer any questions.

To perform the training, it will be ensured that parents had a suitable computer at their disposal. This computer will be placed at a location with limited distractions. Furthermore, to limit distraction during training, children will wear headphones, and no contact with the Internet or other software will be possible on the computer. The post-training assessment will be conducted between two to four weeks after the training.

Intervention

BrainGame Brian is an adaptive, computerized training program in which three EFs, i.e. working memory, inhibition, and cognitive flexibility, are trained embedded in a game world. The game is called *Braingame Brian,* named after the

main character of the game *Brian.* The training consists of 25 training sessions and will be performed daily at home for 40 minutes, 4 days for 6 weeks. During the game, the child has to perform training tasks on EF. Each session contains two blocks (of about 15 min) of the three training tasks of working memory, inhibition, and cognitive flexibility in a fixed order. The first training task is a working memory training task, the second an inhibition training task, and the third a cognitive-flexibility training task. After each block of training tasks, the difficulty level of the training task is automatically adjusted to the child*s maximum level of performance. Motivation is enhanced by elaboration of the game world or extra powers for the game character Brain. The game world gets more and more elaborate from the first to the last sessionand every completed block results in extra powers for Brian. With these extra powers, he can create inventions to help people in his village, resulting in happier village people.

Study burden and risks

There is some burden for parents and children since they have to participate in the program for 4 times a week, for 6 weeks. The training program, however, has been set up as a computer game and has a very child friendly design. Other studies conducted on this training program have shown that most children enjoy to perform the training.

Risk because of participation is negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Children (2-11 years)

Inclusion criteria

* Very preterm children (gestational age < 30 weeks) who participate in a prospective longterm fu study of the Intensive Care Unit Neonatologie of the Emma Children's Hospital AMC Amsterdam.

* Parental permission being approached in the future again

* (Sub)clinical scores T > 60 on the Behavior Rating Inventory of Executive Function (BRIEF)

Exclusion criteria

* IQ scores < 80 as assessed with the short form of the Wechsler Intelligence Scale for Children-III-NL (WISC-III-NL)

* a motor or perceptual handicap too profound to allow use of a computer,

- * no accessibility to a PC with internet connection home
- * a social- economic background which does not permit to follow the study procedures,
- * illness requiring hospital admission during the study inclusion

Study design

Design

Study type: Interventional	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL Recruitment status:

Recruitment stopped

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Start date (anticipated):	09-12-2013
Enrollment:	10
Туре:	Actual

Ethics review

Approved WMO Date: Application type: Review commission:

22-11-2013 First submission 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

No registrations found.

In other registers

Register CCMO

ID NL45094.018.13