Computer based training of executive functions in children with an autism spectrum disorder.

Published: 23-09-2010
Last updated: 30-04-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Developmental disorders NEC
Study type	Interventional

Summary

ID

NL-OMON34346

Source
ToetsingOnline

Brief title
Executive functioning training in autism.

Condition

- Developmental disorders NEC

Synonym
autism, autism spectrum disorder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: autism, computer based, executive functions, training

Outcome measures

Primary outcome

1) Cognitive flexibility: switchcosts (reaction time (RT) on switchtrials compared to non-switchtrials) on the Gender/emotion switch task and Number switch task).

2) Working memory: number correct on the Corsi Block Tapping Task and n-back task.

3) AD/HD symptoms: score on the Disruptive Behavior Disorder rating scale (DBD).

4) Social skills: score on the Children*s Social Behavior Questionnaire (CSBQ).

See studyprotocol for further information about these tasks and questionnaires.

Secondary outcome

1) Inhibition: Stop-reaction time on the Stop task.

2) AD/HD symptoms: number correct on the Sustained attention response task (the SART).

3) EF (all) (Behavior Rating Inventory of Executive Function questionnaire (BRIEF).

4) Quality of Life (Pediatric Quality of Life Inventory, PedsQL).

ToM (score on the Strange Stories Test), punnishment reward sensitivity (score on the BIS/BAS Questionnaire, RT and number correct on a reward vs. neutral version of the Eriksen flanker paradigm), and motivation (score on the VAS scale) will be included as predictors of improvement as a result of the

program.

See studyprotocol for further information about these tasks and questionnaires.

Study description

Background summary

There is an urgent need for effective interventions for children with autism. As for now, most intervention studies in autism focus directly on teaching of social and communicative skills, but are unsuccessful (Charman & Howlin, 2003). Training fundamental abilities such as executive functions (EF) might be susceptible for success. In developmental disorders related to autism, attention deficit/hyperactivity disorder (AD/HD) in particular, executive function interventions have been shown to generalize to domains that were not specifically targeted during the intervention (Klingberg et al., 2005; Prins et al., 2008). The current proposal concerns a randomized clinical trial to study the efficacy of two executive function interventions, working memory training and a cognitive flexibility training, in children with autism.

Study objective

The objective of the study is to improve the trained as wel as other executieve functions. Also the aim of this study is that these functions will improve in everyday life and generalize to other domains, resulting in improvement in behavior, decrease of symptoms and improvement in quality of life.

Study design

Children will be tested on 4 testing sessions. While the children are tested, the parent will be interviewed or asked to fill out questionnaires.
The first testing session (T1) a short intelligence measurement and a theory of mind (ToM) task will be adminstered to the children. The Autisme Diagnostic Interview Revised (ADI-R) will be administered to parents. The ADI-R will be administered to confirm the Autism Spectrum Disorder (ASD) diagnosis.
In testing session 2 (T2), 3 (T3), and 4 (T4) the children will perform EF tasks on the computer and the parent will fill out questionnaires. The training will take place between sessions 2 and 3. The EF tasks are all neuropsychological tasks to measure WM, CogF and respons inhibition with good validity. These tasks will be adapted to make them more attractive to children. The parent's questionnaires include different aspects of behavior (executive functioning, behavioral problems, social behavior, quality of life).

T4 will take place 6 weeks after finnishing the training.

Intervention

In short, 102 children with autism, 8 to 12 years of age, and an estimated IQ above 80 will participate in a randomized controlled clinical trial. Children will be randomly assigned to one of three different conditions; WM training, CogF training or no training. The children will play the game, in which these training conditions are embedded. The total number of training sessions is 25, with a fixed duration of 40 minutes each session. Children are asked to play the game 4-5 times a week for a period of 6 successive weeks, until they have finished all sessions. During each session the participants play the computer game which contains several levels of difficulty. In each session there are two training blocks for each EF. In the Working Memory (WM) training condition, the WM will be trained twice each session, for about 5 minutes each block (10 minutes per session). The training blocks will adapt in difficulty to performance of the child, so that each training block will be somewhat more difficult than the former and WM is actually being trained. The Cognitive flexibility (CogF) training will have a similar set up and duration as the WM training, provided that CogF is being trained. The non-EF training is similar to the WM and CogF training, but the training blocks will be replaced by non-EF tasks. These tasks will be similar to the EF training tasks, but the EF training element is now excluded; the level is and will remain very low, so no EF is actually being trained. This condition will however apply to fastness of reaction, attention and concentration.

Study burden and risks

Four testing sessions (with an avarage of 70 minutes per session) for parents and child. 6 weeks of training, 25 sessions taking 40 minutes each (avarage of 4 times a week). There are no risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

1) A diagnosis of an autism spectrum disorder
2) A diagnosis confirming score on the Social Responsiveness Scale and ADI-R.
3) Age between 8-12 years
4) IQ above 80

Exclusion criteria

1) Epilepsy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2010
Enrollment:	102
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL32255.018.10