Executive functioning training in autism.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26961

Source
Nationaal Trial Register

Brief title
EFA

Health condition

autism, executive functioning.
autisme, executieve functies.

Sponsors and support

Primary sponsor: University of Amsterdam
Source(s) of monetary or material Support: University of Amsterdam

Intervention

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);

5. 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

Objectives:

Hardly any study has focused on ways to reduce executive dysfunctions in children with autism. This is remarkable as there is an urgent need for interventions that alleviate the key symptoms of autism. In related disorders, such as AD/HD, executive function (EF) interventions have been implemented. The observation that children with AD/HD encounter executive dysfunctions has led to very promising EF interventions. The present proposal aims to study the efficacy of three interventions in children with autism: 1) working memory training, 2) cognitive flexibility training and 3) non-EF control training. Working memory and cognitive flexibility are important aspects of EF. The objective is to improve the executive dysfunctions children with autism are known to encounter.

Subjects:

Children with an autism spectrum disorder diagnosis, 8 to 13 years of age, and an estimated IQ above 80 will participate in a randomized controlled clinical trial (n=102).

Methods:

The children will be trained using a computer program with game elements to train working memory (WM) and cognitive flexibility (CogF). The children can move around in a virtual world and will be engaged in several assignments. These assignments are the actual WM and CogF training sessions. The training will take place at home. In one group of children, WM is trained, and in a second group CogF is trained. The third (control) group will play the game, but no specific segment of EF functions will be trained. The non-EF intervention does not focus on one specific domain of executive functioning, but might affect attention, concentration and quickness of reaction.

Hypotheses:

All three training programs will reduce difficulties within major problem areas of autism but differ in their efficacy (cognitive flexibility > working memory > non-EF).

Study objective

Primary outcome measures:

1. Working Memory (WM) training will lead to an increase of WM capacities;

2. Cognitive flexibility (CogF) training will lead to an increase of CogF capacities;

3. The WM training condition, the CogF training condition and the non executive function (non-EF) control condition will lead to a reduction in the presence of AD/HD symptoms in every day life and an increase in social skills. The WM and CogF training will have a more substantial effect than the non-EF control training.

Secondary outcome measures:

1. WM-training and CogF-training will increase the inhibition capacities;

2. WM-training and CogF-training will improve EF functioning in everyday life as reported by parents;

3. The WM training, the CogF-training and the Non-EF control training will improve the Quality of Life. The WM and CogF training will have a more substantial effect than the non-EF control training.

Predictors:

Children who are reward and punishment sensitive, highly motivated or have a relatively well developed ToM, will benefit more from the training program than children who are less reward and punishment sensitive.

Study design

Children will be tested on 4 testing sessions. While the children are tested, the parents 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 response 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 finishing the training.

Intervention

Children will be randomly assigned to one of three different conditions; WM training, CogF training or non-EF training. The children will play a training computergame, 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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Children who are of 8-12 years old;

2. Have an IQ>80;

3. With a prior independent DSM-IV (American Psychiatric Association, 2000) diagnosis of an Autism Spectrum Disorder (ASD).

Exclusion criteria

Children that suffer from epilepsy or grand mal seizures or the like will be excluded from current research.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2010
Enrollment:	102
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-10-2010
Application type:	First submission

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
NTR-new	NL2439

Register	ID
NTR-old	NTR2548
Other	Medical Ethical Commitee AMC : 10/185
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A