

# Improving emotion recognition in children with Autism Spectrum Disorders (ASD) and Borderline Intellectual Functioning (BIF).

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To test the hypothesis that The Transporters will show significant more improvement in contextual understanding of emotions and social functioning in children with ASD and BIF than a control intervention.

|                              |                             |
|------------------------------|-----------------------------|
| <b>Ethical review</b>        | Approved WMO                |
| <b>Status</b>                | Pending                     |
| <b>Health condition type</b> | Developmental disorders NEC |
| <b>Study type</b>            | Interventional              |

## Summary

### ID

NL-OMON38968

### Source

ToetsingOnline

### Brief title

Improving emotion recognition in children with ASD and BIF.

### Condition

- Developmental disorders NEC

### Synonym

autism, autism spectrum disorder

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Karakter Kinder- en Jeugdpsychiater

**Source(s) of monetary or material Support:** Eigen budget Karakter; daarnaast is externe fondswerving nog gaande

## Intervention

**Keyword:** Autism, Borderline Intellectual Functioning, Emotion recognition, Treatment

## Outcome measures

### Primary outcome

Study parameters include neurocognitive performance, social information processing tasks (i.e. reaction times and percentage correct) and measures on social behavioral questionnaires.

### Secondary outcome

n/a

## Study description

### Background summary

Social skills are crucial for adapting to an increasingly complex social world during development. The implications of impaired social skills for mental well-being have called for identifying interventions that enhance social cognitive functioning and specifically target at the core cognitive problems. Most social skills interventions are developed for children with autism spectrum disorders (ASD). However, approximately 50% of individuals with ASD have comorbid intellectual disabilities. The Transporters, an animated series designed to improve emotion comprehension in children with ASD, is a promising intervention for this specific group, given the visual nature, the frequent repetition and the small steps in which new information is being introduced. This study evaluates the efficacy of The Transporters in children with ASD and Borderline Intellectual Functioning (BIF, 70

### Study objective

To test the hypothesis that The Transporters will show significant more improvement in contextual understanding of emotions and social functioning in children with ASD and BIF than a control intervention.

## Study design

Randomized double-blind placebo-controlled intervention study. Subjects are randomly allocated using stratification by age (6;0 - 7;11 and 8;0 - 9;11 years) and comorbid attention deficit hyperactivity disorder (ADHD) (a comorbid diagnosis of ADHD or not), with computer-generated probabilistic minimization.

## Intervention

Two groups of 22 children will be compared. The intervention group will be watching The Transporters DVD, and the control group watches a purpose built DVD of Thomas and Friends, consisting of selected episodes of the series that draw attention to emotions or affect. The duration of the treatment for both groups is 15 minutes, 5 days a week for 4 weeks. In both groups children will be actively supervised by their parents. Before and after the treatment, all children will undergo a neurocognitive assessment (pre- en post- assessment) and parents and teachers will complete several questionnaires. In the week after the last session, the post-assessment will be done and an evaluation of the treatment will take place. Six months after the last treatment session there will be a follow-up.

## Study burden and risks

The burden and risks for the children and parents are minimal, since the largest part of the assessment is care as usual at Karakter. The requested time investment is a total of 4 1/2 hours (distributed over 3 visits). The researchers are skilled in working with children with ASD and BIF and our experience is that children enjoy the cognitive computer \*games\* and watching the DVD\*s.

## Contacts

### Public

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### Scientific

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Children (2-11 years)

### **Inclusion criteria**

1. Children aged between 6 years/0 months and 9 years/11 months, known in psychiatric health care.
2. Autism Spectrum Disorder, classified by the DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, 2000).
3. IQ score between 70 and 85 (BIF).
4. Access to a PC or TV with DVD player.
5. A comorbid ADHD diagnose is allowed, as long as sufficiently treated with medication and dosage stays to be fixed during this intervention.

### **Exclusion criteria**

1. Currently intensive (i.e. weekly) individual or grouptherapy.
2. Diagnosis of one or more of the following comorbid psychiatric disorders:
  - Major depression
  - Bipolar disorder
  - Psychotic disorder
  - Conduct disorder
  - Attachment disorder
  - Serious motor and/or perceptual handicap.
3. Participation in another clinical trial simultaneously.
4. Insufficient motivation to follow the treatment.
5. Medical illness which needs medical treatment.

## **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:       | Pending     |
| Start date (anticipated): | 01-09-2013  |
| Enrollment:               | 44          |
| Type:                     | Anticipated |

## Ethics review

|                    |                                      |
|--------------------|--------------------------------------|
| Approved WMO       |                                      |
| Date:              | 15-11-2013                           |
| Application type:  | First submission                     |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO       |                                      |
| Date:              | 22-09-2015                           |
| Application type:  | Amendment                            |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## 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     | NL45653.091.13 |