Psychiatric and psychological assessment, and course of conduct problems in preschool children

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This study has three aims:1. To investigate the differences in executive functions in 3.5- to 5.5-year-old children with (symptoms or diagnosis of) ODD/CD, ADHD or both, and without diagnosis. And investigate if the differences between these 4...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON30495

Source
ToetsingOnline

Brief title
ADHD and disrupted behavior disorder (DBD) in preschool children

Condition

- Other condition

Synonym
ADHD, behavior problems

Health condition

aandachtstekort/hyperactiviteitsstoornis en oppositioneel-opstandige/antisociale gedragsstoornissen bij kinderen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ADHD, Disrupted behavior disorder (DBD), Preschoolers, Psychiatric Assessment

Outcome measures

Primary outcome

With regard to aim 1:

For the cross-sectional study of differences between the groups in executive control analyses of variance will be used. Factor scores will be calculated on the basis of a factor analysis with scores of the variables of the 7 executive functioning tasks (perhaps corresponding with the three domains: working memory, inhibition and cognitive flexibility).

With regard to aim 2:

The extent to which environmental risk factors explain variance in executive control function will be tested by means of regression analysis. Also, the extent to which executive control function and environmental factors explain variance in disruptive behavior and hyperactivity/attention problems will be tested by means of regression analysis.

With regard to aim3:

The interobserver reliability of the DB-DOS is based upon the judgment of the diagnosis (ADHD, ADD, CD) of 2 observers. The construct validity of the DB-DOS will be investigated by comparing 3 groups (clinical, sub-clinical and non-clinical) for each diagnosis on different C-GAS scores. The clinical

validity of the DB-DOS will be investigated by comparing the judgment of the

observer with the clinical consensus of 2 psychiatrists on basis of all

available information (K-DBDs, C-GAS, ECI, IFS, PSI).

Secondary outcome

There are no secondary study parameters.

Study description

Background summary

Epidemiological studies suggest that the prevalence of ADHD, ODD and CD in preschool children is of the same size as with school age children. However, a valid method for establishing these diagnoses lacks because the criteria are insufficient explicit to age. Also at this young age the border is less clear between what can be seen as normal variation and what can be seen as deviated in the area of aggressive, attention problems, impulsivity, stubborness and anger.

It is likely that high levels of problem behavior decline from 3 years on in a subgroup of preschool children. At present it is not possible within a group of young children with high levels of behavior problems to distinguish between the preschoolers who are persistent in this behavior (and diagnosed with ADHD, ODD or CD) and the preschoolers by whom this behavior naturally declines. It has been shown that 50 % of the children and their families who received intervention did not actually need it. Including many false positives leads to a lower effect size of prevention studies, families are likely to suffer of the negative effects of labeling, and resources are wasted as well. A better recognition of *real children at risk* is necessary.
A method to distinguish the two groups of children is not yet present. Deficits in executive functioning may be considered as precursor of persistent problem behavior. These are higher-order cognitive functions such as inhibition, which have a controlling role in thinking, problem solving and language.
Deficits in executive functions in school aged children and adolescents with ADHD, ODD and CD have been demonstrated but few studies have been conducted in preschool children. It is expected that deficits in executive functioning are present in preschool children with those diagnoses as well as preschoolers who just don*t meet the criteria but are at risk for them. These deficits, together with unfavorable environmental factors are hypothesized to be predictors of persistent problem behavior and in that way to the risk of the development of

ADHD, ODD and CD.

Study objective

This study has three aims:
1. To investigate the differences in executive functions in 3.5- to 5.5-year-old children with (symptoms or diagnosis of) ODD/CD, ADHD or both, and without diagnosis. And investigate if the differences between these 4 groups increase within 18 months.
2. To find out which child (executive control disturbances, intelligence) and parent variables (parental practices, parental distress, depression and impulsivity with the parent and level of education) predict persistence of symptoms of ODD/CD, ADHD or both.
3. To investigate the reliability and validity of a standardized behavior observation which could diagnose ODD, CD and ADHD at preschool age.

Study design

In this project parents of the 3.5- to 5.5-year-old children have the opportunity to participate in a research when their child has behavior problems. A short prospective design (18 months) with 3 measuring moments is followed. For the research about the predictive validity of the executive control disturbances and the environmental factors and the course of behavior problems with preschool children this design is necessary. To study executive control disturbances as a correlate, a cross-sectional design is appropriate. However, in order to assess executive control disturbances as a factor that differentiates the development of ADHD, DBD and ADHD+DBD a longitudinal design is needed. Finally a prospective design is needed to find out the predictive validity in the research of the reliability and validity of the standardized behavior observation.

Study burden and risks

There are no risks associated to this research. The child will be examined three times, but the burdening is limited. The first time (4 hours) will take the longest time, but parent and child only have to come to the clinic for one morning instead of at least twice with a usual psychiatric assessment. After a short talk between the psychiatrist and the parent and two short intelligence tests (30 minutes) with the child there will be a break (15 min.). Further there will be 7 playful executive functioning tasks (60 min.). Three of them are on the computer and with three other tasks they earn a treat. All 7 tasks are very attractive for the child. Afterwards there will be a break of one hour where the parent and child have time to eat, drink or wander around. In the last hour the child will be observed in interaction with the parent and researcher. This observation consists mainly of games, like a puzzle and a marble game. After the observation the children can take a prize home. The

second time (1 hour for the child) the same psychological tests will be administrated, however there will be no behavior observation. The third time (2 * hour) the child will be psychological examined and observed. The research is justified because the burdening of the child and parent is limited, while the parents, who are in uncertainty about the problems of their child, receive well funded information about a possible psychiatric disorder. Also the parents get a recommendation about what they can do on the area of education, parenting and treatment. They will be supported in the realization of this advice.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Age between 3;5 to 5;5 year, living within a family and a minimal score of 90e percentile on the scale of Attention Problems or on the scale of Aggressive Behavior of the Child Behavior Checklist 1.5-5 (CBCL 1.5-5; Achenbach & Rescorla, 2000; Verhulst & van der Ende) or the

Caregiver-Teacher rating Form 1.5-5 (C-TRF 1.5-5; Achenbach & Rescorla, 2000; Verhulst & van der Ende).

Exclusion criteria

Mental retardation (IQ<70), language retardation, and a pervasive developmental disorder or a serious suspicion of this.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-06-2007
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date:	05-06-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL15657.041.06