Better control of aggression

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

Summary

ID

NL-OMON36172

Source
ToetsingOnline

Brief title
Better control of aggression

Condition

- Developmental disorders NEC

Synonym
Disruptive behavior disorder; aggressive behavior

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: NWO-FES gelden

Intervention

Keyword: Disruptive Behavior Disorder, Neurocognition, Treatment effectiveness

Outcome measures

Primary outcome

Aggressive, anti-social and pro-social behaviour; empathy and self regulation

skills, measured at the level of behavior, cognition and neurobiology;

parenting practices. In addition, changes in these measures as a result of

PMTO.

Secondary outcome

not applicable

Study description

Background summary

Children with disruptive behavior disorders (DBD) constitute a heterogeneous group in terms of characteristics, presumed underlying dysfunctions, and type of aggression displayed. Some DBD children show relatively high levels of callous-unemotional traits (CU), presumably because of an underlying empathy deficit, and display increases in reactive as well as instrumental aggression. However, others show low levels of CU traits; instead they have problems in self-regulation and display primarily reactive aggression. Research into the underlying processes of antisocial and aggressive behavior at the level of cognition and neurobiology may increase theoretical understanding and provide important information for prevention and intervention strategies. Therefore, part of the proposed study entails studying cognition and neurobiology in children with DBD in addition to their behavior.
This study will also evaluate factors that influence the effectiveness of Parent Management Training Oregon (PMTO). Previous research has shown that PMTO effectively reduces disruptive behavior by teaching parents more effective ways of parenting. In addition, research has investigated variables in the parents* background that moderate the trainings* effectiveness. However, given that children with DBD are a heterogeneous group, a change in parents* behavior might be more effective in targeting some causes of problem behavior than others. In order to identify the causes of disruptive behavior that are effectively targeted by PMTO, the inclusion of cognitive and neurobiological measures in the proposed study may be of great value.

Study objective

This study has two main objectives. The first objective is to investigate whether children with DBD, when compared to low aggressive and antisocial control children, have neuropsychological and neurobiological abnormalities that may underlie their antisocial and aggressive problem behavior. Specifically we will look at empathic and self- regulation dysfunctions in relation to (types of) aggression and callous-unemotional (CU) traits. A second objective of this study is to investigate the usefulness of this knowledge of the neuropsychological and neurobiological impairments in children with DBD in predicting treatment outcome. We hypothesize that a) PMTO will be effective in decreasing levels of aggression and antisocial behavior in DBD children, b) for children with higher levels of callous-unemotional (CU) traits (and presumed underlying empathy deficits with fear and sadness) PMTO is less effective, as it is known that antisocial behavior in these children is under the influence of social environmental factors too a lesser extent than in children with lower levels of CU traits and c) for children characterized primarily by self-regulation deficits and reactive aggression PMTO is more effective, as self-regulation skills are expected to improve by PMTO. Therefore, we hypothesize that biomarkers (i.e. neuropsychological and neurobiological variables) that are presumably underlying factors in the etiology of different types of aggressive behaviors and CU traits in DBD children are predictive of treatment effectiveness of PMTO.

Study design

Randomized controlled trial, Longitudinal study

Intervention

Parents of DBD children recruited from the clinical centres will all receive PMTO treatment. One in three parents of the DBD children recruited from special education schools and regular primary schools will receive PMTO treatment. The other parents of DBD children will receive care as usual. The control group, recruited at regular primary schools, will also receive care as usual.

Study burden and risks

There are no risks associated with the proposed study. The burden for the children, parents and teachers is kept at a minimal level. The requested time investment for the children is a total of approximately11 hours (distributed over 3 visits), for the parents approximately 4 hours (distributed over 1 visit and 2 phone calls) and for the teachers approximately 1.5 hours (distributed over 3 phone calls). The collection of saliva and physiological measures will pose no significant burden to children: these will not cause discomfort or pain. There will be no clinical diagnostic assessments in this study. If

parents wish clinical diagnostic assessment (medical, psychological), we will refer them to clinicians.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

General inclusion criteria include male gender, age between 8 and 12, voluntary participation, Dutch speaking, signed informed consent from parents, and in the case a child is 12 years, he needs to sign an informed consent as well. For the DBD groups additional inclusion criteria are score above borderline cutoff on CBCL *externalizing behavior* and meeting criteria for ODD or CD. For the Control group, inclusion criteria are no scores above or at borderline cut-offs on the CBCL externalizing scales and not meeting criteria for ODD or CD at the DISC interview .

Exclusion criteria

General exclusion criteria are:
- IQ < 70 for children
- Lack of comprehension of the Dutch language by parents or child
- history of neurological conditions or head injury with loss of consiousness for children

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-05-2012
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date:	20-04-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
Other	ECPW-2011/030
CCMO	NL37299.058.11