ORCHIDS: Study on children's genetic susceptibility to their environment.

No registrations found.

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

Summary

ID

NL-OMON28034

Source
NTR

Brief title
ORCHIDS

Health condition

Externalizing behavior problems.

Sponsors and support

Primary sponsor: Department of Developmental Psychology and Utrecht Centre of Child and Adolescent Studies, Utrecht University.
Source(s) of monetary or material Support: The Netherlands Organization for Scientific Research, no. 452-10-005.

Intervention

Outcome measures

Primary outcome

Primary outcomes are the possible moderating effects of child genotype on the IY intervention effect (i.e., on the decrease in externalizing problems behavior and/or increase in prosocial behavior of the child). The intervention effect will be assessed with the ECBI, the

Matson Evaluation of Social Skills with Youngsters (MESSY), and the Dyadic Parent-Child Interaction Coding System-Revised (DPICS-R).

Secondary outcome

Secondary outcomes will be the observed (changes in) emotional synchronization in parent-child interactions as possible underlying behavioral mechanism to the G×(G)×E interactions.

Study description

Background summary

Background:

A central tenet in developmental psychopathology is that childhood rearing experiences have a major impact on children's development. Recently, candidate genes have been identified that may cause children to be differentially susceptible to these experiences (i.e., susceptibility genes). However, our understanding of the differential impact of parenting is limited at best. Specifically, more experimental research is needed. The ORCHIDS study will investigate gene-(gene-)environment (G×(G)×E) interactions to obtain more insight into a) moderating effects of polymorphisms on the link between parenting and child behavior, and b) behavioral mechanisms that underlie these G×(G)×E interactions in an experimental design.

Methods/design:

The ORCHIDS study is a randomized controlled trial, in which the environment will be manipulated with an intervention (i.e., Incredible Years parent training). In a screening, families with children aged 4-8 who show mild to (sub)clinical behavior problems will be targeted through community records via two Dutch regional healthcare organizations. Assessments in both the intervention and control condition will be conducted at baseline (i.e., pretest), after 6 months (i.e., posttest), and after 10 months (i.e., follow-up).

Discussion:

This study protocol describes the design of a randomized controlled trial that investigates G×(G)×E interactions in the development of child behavior. Two hypotheses will be tested. First, we expect that children in the intervention condition who carry one or more susceptibility genes will show significantly lower levels of problem behavior and higher levels of prosocial behavior after their parent(s) received the Incredible Years training, compared to

children without these genes, or children in the control group. Second, we expect that children carrying one or more susceptibility genes will show a heightened sensitivity to change, and manifest higher emotional synchronization in dyadic interchanges with their parents, leading to either more prosocial behavior or antisocial behavior depending on their parents' behavior.

Study objective

Two hypotheses will be tested. First, we expect differential susceptibility, which means that children in the intervention condition who carry one or more susceptibility genes (i.e., carrying a MAOA low activity (short) allele; DAT 10-repeat allele; DRD4 7-repeat allele; DRD2 A1 allele; 5-HTTLPR short allele; and or a COMT val allele) will show a significantly higher decrease of problem behavior and increase of prosocial behavior after their parent(s) received the parent training, compared to children without such susceptibility genes and children in the control group. In the control group, we expect this same genetic subgroup to show most behavior problems and least prosocial behavior. Second, we expect that emotional synchronization in parent-child interactions will mediate the intervention effect. Specifically, we expect that children who carry one or more susceptibility genes show a higher synchronization to their parents' affect than children without these susceptibility genes. Therefore, we expect these children to benefit most from the increase in parental positive affect and sensitivity induced by the Incredible Years intervention.

Study design

Screening (T1), pretest (T2), posttest (T3), and follow-up (T4).

Intervention

The IY training is aimed at improving parenting skills in order to reduce child behavioral problems, such as aggressive behavior, and enhance competent behavior. The IY training includes 14 to16 weekly two hour sessions. During these sessions parents watch video-vignettes, discuss parenting with each other and practice new techniques in role-plays. Each group will consist of approximately 10 to 12 parents. IY parent training is different from most other parent (management) training programs, in that trainers use a collaborative leading style: They do not instruct, but are part of the group and lead discussions. Many previous randomized trials have shown the program to be effective, also in The Netherlands. Hence, IY parent training is an evidence-based parent training.

Participants in the control condition will receive no intervention, but are allowed –and, in case needed, are assisted– to seek mental health care and parenting support through regular services.

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Eligibility criteria

Inclusion criteria

1. Families with children aged 4-8;

2. Eyberg Child Behavior Checklist (ECBI) score at or above the 75th percentile.

Exclusion criteria

1. Mental retardation of the parent and/or child (IQ ≤ 70);

2. Not mastering the Dutch language.

Study design

Design

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

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2012
Enrollment:	480
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-08-2012
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	NL3443
NTR-old	NTR3594
Other	METC UMCU / NWO : 11-320/K / 452-10-005;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A