

Leiden Consortium Individual Development

No registrations found.

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

Summary

ID

NL-OMON24185

Source

NTR

Brief title

L-CID

Health condition

Externalizing behavior problems; behavioral control; parenting; discipline; social competence

Sponsors and support

Primary sponsor: Leiden University, Faculty of Social and Behavioral Sciences

Source(s) of monetary or material Support: The Consortium on Individual Development is funded through the Gravitation programme of the Dutch Ministry of Education, Culture, and Science and the Netherlands Organization for Scientific Research (NWO grant number 024.001.003); Center for Child and Family Studies; Spinoza Award to Marinus van IJzendoorn; VICI award to Marian Bakermans-Kranenburg (nr 453-09-003)

Intervention

Outcome measures

Primary outcome

The effect of a parenting intervention aimed at improving parental sensitivity and limit-

setting (VIPP-SD) on parental sensitivity and sensitive discipline and on children's behavioral control and social competence.

Secondary outcome

Secondary, we are interested in moderation effects. Are parents with a certain temperamental (reactivity) or genetic make-up (i.e., specific dopamine related genotypes) more susceptible to the intervention?

More exploratory, we are interested in moderation and mediation effects in the intervention effects on child outcomes. Which children are most susceptible to environmental change caused by the intervention? Are children with a neonatal status, a reactive temperament or a certain genetic make-up (i.e., specific dopamine and related genotypes) more susceptible to the VIPP-SD related effects? And, what mechanisms are important in explaining the intervention effects on children's developmental outcomes? Can intervention effects on child behavior be explained by the child's changed neural reactivity, changed hormone levels and/or improved quality of the rearing environment? In addition, what mechanisms are important in explaining intervention effects on parenting behavior? Can intervention effects be explained by changes in neural activity and/or stress level of the parent? These are tertiary hypotheses.

Study description

Background summary

Rationale and objective:

Most children develop well and find their way into society without many problems, but not all children manage to do so. These differences are related to a combination of the child's disposition and the environment in which he or she is raised. However, children are not equally vulnerable to adverse rearing environments, and they do not equally profit from supportive environments. It is thus far unclear which children are most susceptible to the environment, and what the neurobiological mechanisms are of environmental influences on developmental outcomes. In the current study we aim to examine the effect of an interactive parenting intervention (VIPP-SD) on parental sensitivity and sensitive discipline, and on children's behavioral control and social competence. Central questions are: Which children are most susceptible to the

environment, and what are the neurobiological

mechanisms of environmental influences on

developmental outcomes? In addition, which parents are

most susceptible to the intervention and what
neurobiological mechanisms are involved in intervention
effects on parenting behavior?

Study design:

This is an experimental longitudinal study during which families will be followed for six years. Every year, there will be a home visit or a lab visit, during which we will measure several biological, environmental and child characteristics. During two of the three lab visits, we will also measure brain activation using EEG or functional Magnetic Resonance Imaging (fMRI) while the children are performing a computerized decision-making task. We will use structural MRI and Diffusion Tensor Imaging (DTI) to measure underlying brain anatomical processes. The experimental group (40% of the study population, randomly selected) will receive an intervention between the second and third measurement (Video-feedback Intervention to Promote Positive Parenting and Sensitive Discipline [VIPP-SD]; Juffer et al., 2008). This intervention is focused on enhancing sensitive discipline parenting skills. To investigate neurobiological

mechanisms involved in intervention effects on parenting
behavior, a randomly selected sample of 100 parents will
be invited for two parent assessments, one before and
one after the condition.

Study population:

500 families with a healthy twin. Of these families, a
random selection of 100 primary caregivers will be
invited to participate in two separate parent assessments
at the laboratory in which only the primary caregiver
takes part. Of these 100 parents, 50 are randomized to the
intervention condition and 50 to the control condition.

Intervention (if applicable):

The experimental group will receive the VIPP-SD (Juffer et al., 2008), focused on the enhancement of sensitive disciplinary parenting skills. The control group will receive –within the same time frame and with the same frequency- phone calls of a researcher (placebo intervention). During these phone calls, the parents will answer questions about the development of their children.

Main study parameters/endpoints:

The effect of the intervention (VIPP-SD) on enhancement of parental sensitivity and sensitive discipline and on children's behavioral control and social competence.

Study objective

Twelve randomized controlled trials indicated the effectiveness of the Video Feedback to Promote Positive Parenting and Sensitive Discipline in different countries (e.g., Juffer et al., 2008; Juffer & Steele, 2014). The VIPP-SD helps parents to understand and interact with their children in a sensitive way, also when discipline is needed. However, the VIPP-SD may not be equally effective with all families: Some parents and their children may be more susceptible for the intervention than others. Therefore, the central question of this study is: What characterizes parents and children for whom the intervention is most effective? It is expected that children with a mildly compromised neonatal status, a reactive temperament or a certain genetic make-up (i.e., specific dopamine and serotonin related genotypes) are more susceptible to the VIPP-SD related effects. A second

question concerns the mechanisms for change: What factors cause the effects of the VIPP-SD, also on the long term? It is hypothesized that changes in parenting environment caused by the VIPP-SD have positive effects on children's hormone levels, especially those related to stress responses. Also, it is expected that these changes influence children's brain response to aggression provoking stimuli, presuming an improved prefrontal regulation on emotional impulses from the limbic system. In addition, mediating mechanisms of the association between VIPP-SD and positive parenting behavior are investigated. More specifically, parental neurobiological factors (e.g. brain activity) will be investigated as possible mediators of intervention effects on parenting behavior.

Study design

In a longitudinal study families will be followed for six years. Every year, there will be either a home visit or a lab visit with additional ambulatory measurements. The design includes two pretests and four posttests. After the second pretest, the experimental group will receive the VIPP-SD (Juffer et al., 2008), focused on the enhancement of sensitive disciplinary parenting skills. The control group will receive -within the same time frame and with the same frequency- phone calls of a researcher (placebo intervention).

In addition, the subsample of 100 parents (50 control group and 50 experimental group) will be invited to the laboratory twice. The first assessment will take place two weeks before the start of the condition they are randomized to and the second assessment two weeks after finishing the condition they are allocated to.

Intervention

The experimental group (40% of the study population, randomly selected) will receive an intervention between the second and third measurement, the Video-feedback Intervention to promote Positive Parenting and Sensitive Discipline (VIPP-SD; Juffer et al., 2008). This

intervention is focused on enhancing sensitivity and sensitive disciplinary techniques of the primary caregiver. The original version of the intervention has been adapted for the use with twin families in the current study (VIPP-Twins).

Content of the intervention

For the VIPP program families are visited five times at home by an intervener. Every visit lasts for approximately one-and-a-half hours and the visits take place every 2 to 3 weeks. The parent and the children are videotaped during daily situations, such as playing together or mealtime. During the next visit, the video is reviewed with the parent. The intervener focusses on positive and successful interaction moments and shows when positive parenting is effective. The parent is explicitly acknowledged as the expert on her own child. The intervener uses a detailed protocol when discussing the video with the parent. The first four visits have their own themes with respect to sensitivity and sensitive discipline:

1. Exploration versus attachment behavior & Inductive discipline and distraction
2. 'Speaking for the child' & Positive reinforcement
3. Sensitivity chain & Sensitive time-out
4. Sharing emotions & Empathy for the child

The final session is a booster sessions, in which all themes are repeated.

Effectiveness

Twelve randomized controlled trials indicated the effectiveness of the VIPP-SD in a number of countries (for an overview, see Juffer et al., 2008; Juffer & Steele, 2014). These RCTs showed that the VIPP-SD enhanced parental sensitivity and decreased children's externalizing problem behavior. No risks or adverse events were found. As a result, the VIPP-SD is one of the two parenting interventions that are indicated as with established effectiveness in the Database of Effective Youth Intervention from the Netherlands Youth Institute (see www.nji.nl).

Control group

Families in the control group will receive telephone calls from a research assistant during the same period and with the same frequency (placebo intervention). During these telephone calls, parents will be asked about the development of their twins.

Contacts

Public

Centre for Child and Family Studies - Leiden University

S. Euser
PO Box 9555

Leiden 2300RB
The Netherlands
Phone: 0031 (0)71 527 1433

Scientific

Centre for Child and Family Studies - Leiden University

S. Euser
PO Box 9555

Leiden 2300RB
The Netherlands
Phone: 0031 (0)71 527 1433

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Families with a same sex twin
- Native-Dutch speakers
- Parents and grandparents born in Europe (because of genetic analyses)

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Opposite sex twins
- Children with a congenital disability, psychological disorder, chronicle illness, hereditary disease, or a visual or hearing impairment are excluded if the disorder disables the child from performing the behavioral tasks or from participating in the MRI measure.

- Children with a previously diagnosed intellectual disability (IQ < 70), history of neurological or psychiatric illness and/or use of psychotropic medications.
- Participants will be prescreened for contraindications for fMRI, which include metal implants, heart arrhythmia, and claustrophobia.
- For the parental brain activity assessments:

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2014
Enrollment:	1000
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	20-07-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47016

Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5172
NTR-old	NTR5312
CCMO	NL49069.000.14
OMON	NL-OMON47016

Study results