Leiden Consortium Individual Development

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In the current study we examine the effect of a behavioral intervention aimed to improve parental sensitivity on parenting behavior and development of social competence and behavioral control in children. Central questions are: Which parents and...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47016

Source
ToetsingOnline

Brief title
L-CID

Condition

- Other condition

Synonym
Niet van toepassing

Health condition

Het onderzoek heeft geen betrekking op aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: Ministerie van OC&W,Ministerie van OCW en NWO (Zwaartekracht programma nummer 024.001.003)

Intervention

Keyword: Behavioral control, Intervention, Parenting, Randomized controlled trial, Social competence

Outcome measures

Primary outcome

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

Secondary outcome

Moderation:

Which children are most susceptible for the intervention? Are VIPP-SD intervention effects stronger for children with a reactive temperament or with a certain genetic make-up (dopamine and serotonine related genes)?
Which parents are most susceptible for the intervention? Are VIPP-SD intervention effects stronger for parents with a reactive temperament, with a certain genetic make-up (dopamine and serotonine related genes) or certain frontal cortical asymmetry?

Mediation:

Via which (neurobiological) mechanisms does the intervention affect child development? Can the intervention effects on behavioral outcomes be explained

by a changed neural reactivity of the child, changed cortisol levels, and/or improved quality of the parenting environment, in particular the amount of chaos in the direct environment of the child?

Via which processes does the intervention lead to an improvement in sensitive parenting? Can the intervention effects on parenting be explained by changes in neural processing of emotions and/or behavioral control and/or parental stress levels?

Study description

Background summary

Most children develop well and find their way into society without many problems, but not all children manage to do so. We know that this difference is related to a combination of the child*s disposition and the environment in which he or she is raised. Children are not equally vulnerable to adverse rearing enviornment, and they do not equally profit from supportive environments.

Study objective

In the current study we examine the effect of a behavioral intervention aimed to improve parental sensitivity on parenting behavior and development of social competence and behavioral control in children. Central questions are: Which parents and which children are most susceptible for the intervention, and what neurobiological mechanisms play a role in the intervention effect on parenting and child development?

Study design

In the current longitudinal randomized trial, families will be followed during a period of six years. There will be annual measurements, during home or laboratory visits. In the week following each annual visit, parents will perform several ambulatory measurements at home. Further, the experimental group (40% of the families) will receive an intervention between the second and third measurement (Video-feedback Intervention to Promote Positive Parenting and Sensitive Dicipline [VIPP-SD]; Juffer et al., 2008). This intervention aims to improve parental sensivity and sensitive discipline. In addition, a group of

100 (40 experimental group and 60 control group) randomly selected parents will be invited for two parentvisits, one before the intervention and one after the intervention.

Intervention

Families in the experimental condition will receive the VIPP-SD (Juffer et al., 2008), a behavioral intervention aimed at improving parental sensitivity and sensitive discipline. Families in the control condition will receive a dummy intervention during the same period and with the same frequency. This dummy intervention consists of phone calls from a research assistant, in which the parent is asked about the development of his/her children.

Study burden and risks

There are no risks associated with participation. The annual visits will last no longer than half a day (3 hours). Parents are asked to fill out some questionnaires before each of the visits. Further, parents receive materials to perform some ambulatory measures in the week following each annual visit. These ambulatory measures will take approximately three and a half hours per child, distributed over a period of four days. The two parent visits before and after the intervention or dummy intervention will take place at Leiden University and last 1,5 hours each. Multiple randomized controlled trial demonstrated the effectiveness of the VIPP-SD in improving parental sensivity and indicated that the invervention has no negative effects (zie e.g., Bakermans-Kranenburg, Van IJzendoorn, Mesman, Alink, & Juffer, 2008; Juffer et al., 2009; Kalinauskiene et al., 2009; Van Zeijl et al., 2006).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- Twins
- Speaks Dutch
- Parents and grandparents are born in Europe
- Twins have the same gender

Exclusion criteria

- Twins have a different gender
- Children with a congenital abnormality, psychological disorder, chronical illness, hereditary disorder or ear or eye malfunction are excluded if their disorder prohibits them from participating in any of the behavioral or EEG/ERG measures.

Study design

Design

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

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2014
Enrollment:	690
Type:	Anticipated

Ethics review

Approved WMO Date:	31-10-2014
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	08-08-2016
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	18-09-2017
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	30-01-2018
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	28-01-2019
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO	

Date:	18-06-2019
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	09-09-2019
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	04-05-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	17-06-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24185
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL49069.000.14
OMON	NL-OMON24185