Brain development in Childhood and emerging Adolescence

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

Summary

ID

NL-OMON40861

Source
ToetsingOnline

Brief title
Brain development in Childhood and emerging Adolescence

Condition

- Other condition

Synonym
not applicable

Health condition

Het onderzoek heeft geen betrekking op aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden, Faculteit Sociale Wetenschappen
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, Development, Imaging, Social competence

Outcome measures

Primary outcome

The effect of the intervention (VIPP-SD) on children*s behavioral control and

social competence.

Secondary outcome

Child factors moderating the association between environmental influences and

child social competence and behavioural control.

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. Not all children are equally vulnerable for harmful environments, however, on the other hand, not all children equally benefit from the positive effects of a supportive environment.
In the last two decades, researchers have discovered much about the fascinating changes in how the brain develops during childhood and emerging adolescence. This has led to new insights into how children adapt to quickly changing social environments, such as school, social relations, friendships, etc. (Crone & Dahl, 2012). However, much less is understood about why some children adapt easier than others. Currently, the leading hypothesis is that temperamental differences may result in differential susceptibility to the child*s environment, such as the home situations and influence of peers (Belsky & de Haan, 2011). That is to say, some children may be more sensitive to

positive or negative environmental factors than others.

Study objective

This study aims to investigate the effects of a behavioral intervention which is aimed at the improvementenhancing of parental sensitivity and sensitive disciplinary techniques to on the development of children*s social competence and behavioral control of the children. Furthermore, this study aims to investigate how the developing brain is shaped by the interplay of personal and environmental factors using longitudinal brain imaging investigation. Investigators of different backgrounds will combine efforts to make significant steps in understanding this dynamic interaction. Central questions of this study are: Which children are most susceptible to the intervention, and what neurobiological mechanisms play a role in the effect of the intervention on children*s development.

Study design

In a longitudinal study families will be followed for six years. Every year, there will be either a home or a laboratory visit. During two of the laboratory visits, we will measure brain activation using functional Magnetic Resonance Imaging (fMRI) while participants are performing two computerized tasks. Also, we will use structural MRI and Diffusion Tensor Imaging (DTI) to measure underlying brain anatomical processes. Following these annual visits, ambulatory measurements will take place at home. The study uses randomized control design. The experimental group (half of the sample) 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), which is aimed at enhancing sensitive parenting skills.

Intervention

The experimental group will receive the VIPP-SD (Juffer et al., 2008), which is aimed at enhancing sensitive parenting skills, also in the context of discipline. The control group will receive -within the same time frame and with the same frequency- phone calls of a researcher (dummy intervention). During these phone calls, the parents will answer questions about the development of their children.

Study burden and risks

There are no known risks associated with participating in the proposed measurements. The cognitive and behavioral tasks have been used by the research group in previous studies. MRI is a noninvasive technique involving no catheterizations or introduction of exogenous tracers. Numerous children and adults have undergone magnetic resonance studies without apparent harmful

consequences. Some people become claustrophobic while inside the magnet and in these cases the study will be terminated immediately at the subject's request. The only absolute contraindications to MRI studies are the presence of intracranial or intraocular metal, or a pacemaker. Relative contraindications include claustrophobia. Subjects who may have metallic foreign bodies in the eyes or head, or who have cardiac pacemakers will be excluded because of potential contraindications of MRI in such subjects. Although there is no direct benefit to the participants from this proposed research, there are greater benefits to society from the potential knowledge gained from this study. This knowledge about normal development is critical to aid in the understanding of cases of abnormal development, as seen in children with autism spectrum disorder, depression, schizophrenia, Attention Deficit Hyperactivity Disorder, Obsessive-Compulsive Disorder, Tourette*s syndrome, or traumatic brain injury.
Several randomized controlled trial indicated the effectiveness of the VIPP-SD in improving parental sensitivity and showed that the intervention has no harmful effects (e.g., Bakermans-Kranenburg, Van IJzendoorn, Mesman, Alink, & Juffer, 2008; Juffer et al., 2008; 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
- Twins are 7 or 8 years old during the first measurement.

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 MRI measures.
- Mental retardation (IQ<70) earlier diagnosed.
- MRI contradictions

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2015
Enrollment:	690
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	27-11-2014
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	27-11-2014
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	19-05-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	07-07-2015
Application type:	Amendment
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:	30-01-2018

Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	29-08-2019
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	11-10-2019
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	21-06-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	02-03-2023
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	04-04-2024
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

No registrations found.

In other registers

Register	ID
CCMO	NL50277.058.14