

A Good Start (Een goed begin)

No registrations found.

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

Summary

ID

NL-OMON28516

Source

Nationaal Trial Register

Brief title

MINDS - Leiden

Health condition

behavioral problems, externalizing behavior, aggressive behavior

(gedragsproblemen, externaliserend gedrag, agressie)

Sponsors and support

Primary sponsor: Clinical Child and Adolescent Studies, Leiden University, Leiden, The Netherlands

Source(s) of monetary or material Support: This study is funded by the Netherlands Organization for Scientific Research (NWO), grant number: 056-23-001 (Principal Investigators: H. Swaab & S. H. M. van Goozen).

Intervention

Outcome measures

Primary outcome

Child parameters:

- Neurobiological: stress reactivity of the autonomic nervous system functioning and hypothalamic-pituitary-hypothalamic-pituitary-adrennal [HPA] axis activity
- Neurocognitive: precursors of executive functioning, Theory of mind, verbal abilities
- Temperament
- Behavioral: aggressive behavior

Maternal parameters:

- Neurobiological: stress reactivity of the hypothalamic-pituitary-hypothalamic-pituitary-adrennal [HPA] axis activity
- Neurocognitive: reflective functioning, executive functioning, emotion regulation
- Behavioral: parenting, parenting stress, self-efficacy

Secondary outcome

Child parameters:

- Developmental level
- Birth outcomes (e.g. length, weight, Apgar-score)
- Health

Maternal parameters:

- Psychopathology/ mental health
- Life style (alcohol, drugs and smoking)
- Stressful life events
- SES (e.g. work status, education)
- Social network
- Health
- Use of other interventions

Study description

Background summary

In the Mother-Infant Neurodevelopment Study (MINDS)- Leiden is a longitudinal study investigating 1) mechanisms through which neurobiological, neurocognitive and social-environmental factors increase risk for emotional and behavioural problems in early childhood, 2) effects of an intensive home-visiting program for first-time mothers at high-risk on child neurobiological, neurocognitive and emotional and behavioural development, and 3) which factors (neurobiological, neurocognitive and social-environmental) predict variation in effects of the home-visiting program on child emotional and behavioural outcomes. Families are classified as low-risk or high-risk based on the presence of one or more risk factors (based on World Health Organization-criteria: e.g. presence of maternal psychopathology, substance use, and social adversity). High-risk women are randomly assigned to the intervention or high-risk control group. Six assessment waves are conducted within a four-year period, starting at 27 gestational weeks until the child is 42 months old. This study will help identifying specific biomarkers, precursors of neurocognitive functions and temperamental factors in infancy, facilitating the detection of children at risk for later emotional and behaviour problems. Furthermore, this study may yield insights into effective, targeted, and tailor-made components of prevention programs, ultimately reducing the psychological and economic costs of mental health problems to society.

Study objective

Behavioral problems, especially externalizing behavior such as aggression, starting in the early development of life has a poor prognosis. A large body of research on the etiology of antisocial behavior has focused on the role of environmental factors. A more recent area of research has focused on neurobiological and neurocognitive factors involved in the development of aggressive behavior. However, most of this research involves children in which aggressive behavior is already part of their behavioral repertoire. The focus of this

study is on the first four years of life, when behavioral problems (i.e. aggressive behavior) first appear in the child's behavioral repertoire. To prevent social, emotional and cognitive problems later in development and to prevent long lasting and expensive treatment programs, it is important to develop evidence-based treatment and preventive programs.

In the present study three important questions are addressed. First, which neurobiological and neurocognitive factors predict (directly, indirectly or in interaction with social-environmental factors) emotional and behavioral problems – specifically aggressive behavior – in the first four years of life? Second, what are the effects of an intensive home-visiting program for first-time mothers at risk on neurobiological, neurocognitive and emotional and behavioral development in children in the first years of life? Third, which factors (neurobiological, neurocognitive and social-environmental) predict variation in effects of the home-visiting program on child emotional and behavioral outcomes?

Study design

Assessments take place prenatally at 27 gestational weeks, and postnatally at 6, 12, 20, 30 and 42 months

Intervention

Half of the high-risk families take part in an intensive home-visiting program based on 'Minding the baby' (MTB). This preventive intervention program consists of home visits carried out by 'coaches', starting by the 28th week of pregnancy with weekly visits and continuing through the infant's first year. The home visits are then tapered to every other week through the child's second year. During the home visits, the coaches carry out three major activities: (a) stimulating maternal reflective functioning, (b) promoting secure attachment, (c) attention for mental and physical health in mother and child, and child's development.

The high-risk and low-risk control subjects will receive the casual care.

Contacts

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Eligibility criteria

Inclusion criteria

Dutch-speaking primiparous women between 17 and 25 years old with uncomplicated pregnancies were eligible to participate.

The current study discriminates between high-risk (HR) and low-risk (LR) families. Classification to the HR-group was determined during pregnancy based on the following risk factors: 1) positive screening on current psychiatric disorder(s) or substance use (alcohol, tobacco and/or drugs) during pregnancy; or 2) presence of two or more of the following risk factors: single status (biological father not involved), unemployment, financial problems, no secondary education, limited social support network (<4 individuals listed in network), and young maternal age (<20 years). In case only one risk factor was present - other than an indication for current psychiatric disorder(s) or substance use - women were discussed in a clinical expert meeting to determine whether placement in the HR-group was appropriate.

Exclusion criteria

Exclusion criteria were heavy drug addiction or severe psychiatric or psychotic disorder, an intelligence quotient (IQ) below 70, major acute or significant chronic illness in the mother or a disorder or syndrome in the child, which would affect normal development.

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:	Recruiting
Start date (anticipated):	01-02-2011
Enrollment:	275
Type:	Anticipated

Ethics review

Positive opinion	
Date:	14-06-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43843
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5773
NTR-old	NTR5927
CCMO	NL39303.058.12
OMON	NL-OMON43843

Study results

Summary results

Smaling, H.J.A., Huijbregts S.C.J., Van der Heijden, K.B., Van Goozen, S.H.M. & Swaab, H. (accepted). Maternal reflective functioning as a multidimensional construct: differential associations with children's temperament and externalizing behavior. *Infant Behavior and Development*.

Smaling, H.J.A., Huijbregts S.C.J., Van der Heijden, K.B., Hay, D.F., Van Goozen, S.H.M. & Swaab, H. (accepted). Prenatal reflective functioning and development of aggression in infancy: The role of maternal intrusiveness and sensitivity. *Journal of Abnormal Child Psychology*.

Smaling, H.J.A., Huijbregts S.C.J., Suurland J., Van der Heijden, K.B., Mesman, J., Van Goozen, S.H.M., & Swaab, H. (2016). Prenatal reflective functioning and maternal interactive behavior during free play, the Still-Face Paradigm, and two teaching tasks. *Infancy*. n/a- n/a. doi: 10.1111/infa.12137

Suurland, J., Van der Heijden, K.B., Smaling, H.J.A., Huijbregts, S.C.J., Van Goozen, S.H.M., & Swaab, H. (accepted). Maternal risk status predicts autonomic nervous system reactivity and recovery in infants. *Development and Psychopathology*.

Smaling, H.J.A., Huijbregts S.C.J., Suurland J., Van der Heijden K.B., Van Goozen, S.H.M. & Swaab, H. (2015). Prenatal reflective functioning in primiparous women with a high-risk profile. *Infant Mental Health Journal*, 36(3), 251-261. doi: 10.1002/imhj.21506