A good start: An early intervention to prevent the development of antisocial behavior in infants

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43843

Source
ToetsingOnline

Brief title
A good start

Condition

- Other condition

Synonym
-

Health condition

het onderzoek richt zich niet op bepaalde aandoeningen maar meer op een verzameling van factoren die maken dat een (aanstaande) moeder verminderd in staat is om zich goed aan te passen aan het moederschap, dat kunnen problemen zijn in de psychische gezondheid, financiele situatie, huisvesting, sociale steun, levensstijl, werkloosheid, uitval in het onderwijs en dergelijke

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: NWO

Intervention

Keyword: Aggression, High risk, Infants, Intervention

Outcome measures

Primary outcome

The assessments will focus on (1) maternal self-efficacy in the nurturing role, life style and psychopathology, (2) the neurobiological (HPA axis and ANS functioning), neurocognitive (e.g. executive functioning) and socio-emotional development (e.g precursors to Theory of Mind, emotional reactivity and regulation) of the child, and (3) the quality of parenting and the parent-child relation.

Secondary outcome

A secondary aim of this study is to evaluate the (behavioral, personality-, socio-demographic) profile of mother*s who benefit most from the intervention versus mothers who do not benefit or benefit less from the intervention. These secondary study parameters are maternal parameters such as Psychopathology/ mental health, Life style (alcohol, drugs and smoking), Personality, Intelligence, Demographics (e.g. work status, education, relationship status).

Study description

Background summary

Aggressive behavior 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 two 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.

Study objective

The first objective of this study is to gain insight in which neurocognitive and neurobiological processes underlie the development of externalizing behavior (in specific aggressive behavior) in the first two years of life. The second objective is to examine the effects of an intensive home visiting program for first time mothers at risk on child neurocognitive and neurobiological functioning, and the working mechanisms underlying the effects of this program. A secondary objective of this study is to evaluate the social and cognitive profile of mothers who benefit most versus mothers who benefit less from the program.

Study design

Randomized control intervention study, three groups (one intervention and two control groups). Subjects assigned to the high risk group (presence of > 1 risk factor) are randomly allocated to either the intervention group (N=60) or the (high risk) control group (N=100). Subjects in the low risk group (presence of <2 risk factors) will serve as (low risk) normal control group (N=100). The study consists of five measurement moments across three years, at the 27th week of pregnancy and 6, 12, 20, 30 and 45 months post partum.

Intervention

Half of the high risk subjects will receive an intervention. The intervention consists of home visits, 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

control subjects will receive the casual care.

Study burden and risks

Participation includes five assessments over a three year period (three home visits (T1, T2, T4), and three visits to the Babylab (T3, T5, T6)). The assessments will last no more than two and a half hours. There are no known risks associated with participating in this study and the intervention. The physical burden for the children participating is minimal and will consist of taking several saliva samples (at T3, T5 and T6) and having attached to their bodies the heart rate and respiration monitoring equipment (at T2, T3, T5 and T6). Serval saliva samples will also be taken from the mothers (at T3 and T5). The most important benefits for mothers and children in the intervention group are increased knowledge of early child development in general and in particular the mother learns to understand her child*s behavior, feelings and needs, and to adequately respond to her child. In addition, the mother is given help with the organization of her own life, home, social network, education and work leading to a more positive environment for mother and child. For subjects who participate in this study but not in the intervention, there are benefits from the potential knowledge gained from this study. They are stimulated to actively think about their role as a (becoming) mother and the development of their child. In this way, and by actively involving the mothers in the child assessments, they may gain more insight in the development of their child.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Aged between 17 and 25 (at recruitment/consent)
- Having a first child
- Recruited no later than 27th week of the pregnancy
- Competence in Dutch language
Regarding the assignment to the high risk group, the following list of criteria is used. A subject is assigned to the high risk group in case more than one risk factor is present:
- Unemployed
- Housing problems
- Poverty / financial problems
- Single or varying partners
- No or little social support
- Psychiatric disorder or psychosocial problems
- Substance use/abuse (alcohol, smoking, drugs)

Exclusion criteria

- Heavy drug addiction or severe psychiatric or psychotic disorder, which requires more heavy psychiatric help
- IQ < 70
- Major acute or significant chronic illness in the mother
- Disorder or syndrome in the child which will affect normal development

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-07-2012
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	26-06-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	08-09-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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: 28516
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL39303.058.12