YOUth babycohort framework protocol

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON53137

Source
ToetsingOnline

Brief title
YOUth Baby framework

Condition

- Other condition
- Psychiatric disorders NEC

Synonym
behavior, Brain

Health condition

Neurocognitieve en gedragsontwikkeling

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Zwaartekracht

subsidie

Intervention

Keyword: Behavioral development, Birth Cohort, General functioning (psychosocial), Neurocognitive (brain and cognitive) development

Outcome measures

Primary outcome

- Neurocognitive development: brain development (EEG/ERP) and cognitive

development (eyetracking, IQ and behavioral assessments)

- Specific behavioral outcomes: social competence and behavioral control

(questionnaires and behavioral assessments)

Secondary outcome

- Psychosocial functioning (questionnaires)

- Academic achievements (questionnaires and merging with external databases)

- Problem behavior (questionnaires and merging with external databases)

- Psychiatric disorders (questionnaires and merging with external databases)

Study description

Background summary

Childhood (including puberty) is characterized by rapid and profound changes in the brain accompanied by biological and psychological change; consequently, this is a critical period for the development of behavioral, psychological and psychiatric problems. Indeed, across child development, psychiatric disorders are the most important cause of burden of disease in high-income countries. For instance, 23% of all disability-adjusted life years (DALYs) in children between 0-14 years old are attributable to psychiatric disorders. Moreover, children without psychiatric disorders also often experience behavioral problems that are equally disruptive, at a personal, familial and societal level. This makes it crucial to grasp how such behavioral changes arise, and to what extent these changes are related to changes in brain development. However, despite the

obvious relevance of relating brain development to behavioral development, there is a paucity of longitudinal studies examining structure and function, including cognition, of the brain in childhood. There is also little insight into how biological, child-related and environmental factors interact in shaping brain and behavior during the course of development.
The YOUth cohort focuses on neurocognitive development (brain and cognitive development) involved in two core characteristics of behavioral development: social competence and behavioral control. From an early age, deficiencies in social competence and behavioral control have been linked to a variety of behavioral, psychological and psychiatric disorders. For our studies we will use a longitudinal cohort design, since the (limited) research explaining variation in child and adolescent problematic behaviors has mostly been conducted in cross-sectional and case-control studies. A longitudinal cohort design is better suited to study the effect of biological, child-related and environmental characteristics on the developing brain (neurocognitive development) and subsequently on the developing behavior. We will cover the whole range of variation in behavioral development, ranging from uncomplicated development, through problem behavior, to psychiatric disorders.
A primary motivation of the proposed research in this framework protocol is not only to advance scientific knowledge about developing brains and behaviors, but also to inform on policy-level questions. Key features of the proposed research program have implications for strategies to help identify individual genetic or acquired susceptibility, and optimal developmental timing for preventive efforts. Thereby, it will provide approaches to identify high-risk individuals in combination with high-risk social environments, and create opportunities for influencing these psychosocial sensitivities in positive ways; that is, by offering crucial advice for taking care of vulnerable youth.

Study objective

This cohort study aims to explain why some children develop well and others fail to thrive in society. To this purpose, we examine how neurocognitive development mediates the association between developmental changes in biological, child-related and environmental factors, and specific behavioral development and general functioning in children.

Study design

A prospective population-based longitudinal cohort study in the general population with repeated measurements during pregnancy, and after birth at 4-7 months, 9-12 months, 2-5 years, 5-8 years.

Study burden and risks

For the parents, the burden associated with participation consists of: a range of questionnaires (approximately 60-120 minutes every measurement wave), blood

and buccal cell donation (only at entry), and an IQ test (once). Additionally, for the mothers the burden associated with participation comprises two 3D ultrasounds during pregnancy and hair sample collection at 30 weeks pregnancy. For the children, the burden associated with participation consists of EEG/ERP, behavioral and cognitive tests, a parent-child interaction session, and buccal cell donation (each measurement wave). Every testing day, from 2-5 years of age onwards, a hair sample of the child will be collected. Cord blood is collected at birth. We also measure their IQ at the final measurement. There are minimal risks associated with each of these subparts.
The YOUth cohort aims to investigate how neurocognitive development in the general population mediates the influence of biological, child-related and environmental determinants on behavioral development in children. The nature of our research questions makes it immediately clear that our research can only be performed in children.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Children (2-11 years)
Babies and toddlers (28 days-23 months)

Inclusion criteria

- Pregnant women living in Utrecht or surrounding areas

Exclusion criteria

- Not willing to provide informed consent
- Not allowing unexpected findings to be reported to themselves or their general practitioners.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-07-2015
Enrollment:	9000
Type:	Actual

Ethics review

Approved WMO

Date:	18-03-2015
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	30-04-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	27-05-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	03-06-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-08-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-10-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	09-12-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	20-04-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-07-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	16-08-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	

Date:	30-11-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	21-12-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	19-01-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-03-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-04-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	29-11-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	17-01-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	19-12-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-02-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	

Date:	04-07-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	03-01-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-03-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-09-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-05-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	17-06-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	07-09-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-11-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-05-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	

Date:	31-08-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	24-01-2023
Application type:	Amendment
Review commission:	METC NedMec

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	NL51465.041.14