CID PILOT STUDY: A test of the design, recruitment, and methods for the Utrecht baby and adolescent cohort studies.

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Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON40994

Source
ToetsingOnline

Brief title
CID PILOT STUDY

Condition

- Other condition

Synonym
behavioral control, brain development, social competence

Health condition

Psychosociale ontwikkeling

Research involving
Human

Sponsors and support

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

Intervention

Keyword: children, cohort, pilot

Outcome measures

Primary outcome

The main evaluation criteria for the pilot study are: The number of measures failed due to baby*s fatigue or loss of attention; the observed and registered burden of the testing for the babies and children; the self-reported burden for the parents; total workload for the measurement team and feasiblity of the planning and the day scripts; costs and efficiency of the recruitment procedure and resulting response rates.

Secondary outcome

Efficiency of two conditions of measurement for the baby cohort; data reliability obtained in the two conditions of measurement; preference of parents for measurement location.

Study description

Background summary

The large Utrecht CID study will provide information on the interaction between environmental and biological determinants on children*s behaviour, and the role of brain development in the development of a child*s behaviour. The study will thus shed new light on why some children thrive and others do not. Preceding the design of the two large cohorts of the CID Utrecht study, a pilot study is proposed. The pilot study is meant to give an empirical basis for the specific

design questions that the study is facing and to optimise the logistics and course of measurement.

Study objective

The primary objective of the pilot study is to optimise the design of the large cohort study and test the logistics and course of measurement. Furthermore, the pilot study allows us to assess and adapt the burden of the measurements for the children and parents. Secondary objectives are the comparison of baby measures taken at home with measures taken at the research center; and the estimation of the short-term reliability of the EEG measurements in babies.

Study design

Pilot study for observational longitudinal cohort study. Measures of brain activity are recorded during the presentation of social stimuli and the execution of attentional tasks, using EEG registration and MRI scanning. In addition, cognitive tests and behavioural tasks are carried out. A split-ballot design is used to compare baby measures taken at home with measures taken at the research center.

Study burden and risks

Since the focus of the Utrecht CID cohort study is on brain development from birth into adolescence, the general cohort study can only be performed in children: young babies as well as pre-adolescents. To be truly predictive for the main study, the pilot study needs to be performed in the same age groups. Children and parents have no direct personal benefit from the study. There are no known risks associated with participation in the proposed research and the burden is estimated to be low (a total course of 1,5 days, with an effective measurement time of about 90 minutes to 2,5 hours).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Babies: 9-11 month old
Adolescents: between 9 years 11 months and 10 years 1 month old

Exclusion criteria

- Premature born (<32 weeks gestational age)
- Children with a congenital disease
- For the 10 year old children: the standard list of exclusion criteria for MRI (irrremovable metal objects, etc.)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	120
Type:	Anticipated

Ethics review

Not approved

Date:	14-04-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL48126.041.14