The neurocognitive development of infants and young children

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A systematic investigation of the neurocognitive underpinnings of cognitive development in young children.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON37377

Source
ToetsingOnline

Brief title
Neurocognitive development

Condition

- Other condition

Synonym
not applicable

Health condition

geen betrekking op aandoeningen, het gaat om niet-therapeutisch, groepsgebonden onderzoek

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: Ministerie van OC&W,NWO,EU onderzoekssubsidies

Intervention

Keyword: early neurocognitive development, EEG, eye tracking, fNIRS

Outcome measures

Primary outcome

Depending on the specific experiment, the main dependent measures are:

• Oxygenated hemoglobin concentration changes (µmol) (fNIRS)

• Time locked voltage changes (µV) at different electrode sites (EEG)

• Power changes (µV2) at different electrode sites (EEG)

• Location of eye gaze and timing of eye movements

Secondary outcome

Not applicable

Study description

Background summary

This proposal is a general proposal for neurocognitive research studying the neurocognitive development of children from 3 months of age up to 4 years. The research described in this proposal is fundamental and aims at understanding the normal cognitive development of healthy children. The ultimate goal of our research program is to increase our insight into early social-cognitive development. Research questions of our research centre are for example: How do infants learn to speak and understand language? How do young children make sense of what other people do, feel, and think? How do children become proficient actors themselves and how do they ultimately learn to act together with others? And which neurocognitive mechanisms support the development of these social-cognitive skills?
More concretely, research questions will be operationalized as follows:

1) Until / from which age do children process the information provided in condition A differently than information provided in condition B?
2) Does a child who is proficient in skill X process information from condition A differently than information from condition B? (in contrast to children who are not yet proficient in skill X)
3) Is the score on behavioural measure X of an individual associated with the difference in information processing between condition A and B?
Neurocognitive processing will be assessed using EEG or fNIRS. In some experiments, gaze data will be measured (gathered by means of a Tobii near-infrared eye-tracker). Different experiments will address specific research questions. In such an experiment, the skill could be for instance *independent walking*, *clapping hands*, or *pronouncing babbles*. For behavioural measures, the researchers will make use of validated questionnaires for the parents (e.g., the Dutch version of the MacArthur-Bates Communicative Development Inventory, Zink & Lejaegere, 2001), or scales assessing behavioural development such as the Bayley Scales of Infant Development (van der Meulen, Ruiter, Lutje Spelberg, & Smrkovsky, 2002). The children will be presented with different stimulus material, consisting of visual, auditory, or tactile stimuli, and possibly a combination thereof. Furthermore, depending on the research question and the age group, the researcher might offer tasks (such as simple games) suited to the level of development of the age group. In such experiments, the focus is on associations between behaviour and brain responses.

Study objective

A systematic investigation of the neurocognitive underpinnings of cognitive development in young children.

Study design

We will make use of three types of designs: 1) within subject comparisons, 2) between subjects comparisons: different age groups, 3) between subjects comparisons: same age group, but different scores on behavioural tasks / skills.

Study burden and risks

The studies aim to investigate research questions from the field of developmental cognitive neuroscience. Necessarily, the study involves infants and young children as participants. There are no known risks associated with participation in the proposed research. The burden for both participant and caregiver are kept as low as possible, see for a more elaborate description the research protocol (page 18-26).

Contacts

Public
Radboud Universiteit Nijmegen

P.O. Box 9104
6500 HE Nijmegen
NL
Scientific
Radboud Universiteit Nijmegen

P.O. Box 9104
6500 HE Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Infants can be included in the proposed study if they have no history of pre- and perinatal complications and were born after a gestation period of at least 37 weeks. Twins are allowed to the study.

Exclusion criteria

General exclusion criteria are sensory impairments, organic brain disorders, and serious pre- or perinatal complications (e.g., premature birth, asphyxia etc.).

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2012
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date:	01-11-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL39352.091.12