Reliability of EEG, ERP and eye tracking measurements in infants

Published: 16-06-2014
Last updated: 21-04-2024

The primary aim of the current study is to investigate the test-retest reliability of background EEG, ERP and eye tracking measurements in specific tasks in infants of 10 months old. This will provide important general information for interpretation…

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

Summary

ID

NL-OMON40656

Source
ToetsingOnline

Brief title
Reliability study in infants

Condition

- Other condition

Synonym
n.v.t.

Health condition

n.v.t.

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,NWO zwaartekracht subsidie 024.001.003

Intervention

Keyword: Babies, Brainfunction, Reliability

Outcome measures

Primary outcome

Our evaluation of the test-retest reliability of measures of brain development

will be based on the following outcomes:

- ERP peaks related to face processing in infants, specifically the amplitude

and latency of the so-called N290 peak, in response to photographs of faces

with different emotional expressions (emotional face task).

- Background EEG, as reflected in power in specific frequency bands in the EEG,

especially gamma power, to social and nonsocial film videos (background EEG

task)

- Length and number of visual fixations to stimuli that test different stages

of attention (gap/overlap task).

Secondary outcome

None

Study description

Background summary

Electroencephalogram (EEG) measurements (including Event Related Potentials, or ERPs) in infants play a pivotal role in research on functional brain

development, because they can be used to measure, amongst others, emotional and visual information processing in infants. In addition, eye tracking, which provides information on eye movements of an infant, is increasingly used to measure the focus and duration of attention of infants. Using these methods we gradually gain insight in the functional development of the brain in the first years of life. However, surprisingly little is known about the test-retest reliability of EEG, ERPs, and eye tracking measurements in infants. Test-retest reliability is an important property for measures used in developmental studies, because it is crucial to know whether observed differences in these measures at different time points are due to developmental changes or to measurement error. Current knowledge of the reliability of EEG, ERP and eye tracking measures is limited to adults and older children, and cannot simply be extended to infants.

Study objective

The primary aim of the current study is to investigate the test-retest reliability of background EEG, ERP and eye tracking measurements in specific tasks in infants of 10 months old. This will provide important general information for interpretation of studies on brain function in infants.

Study design

The study involves an observational non-invasive study including two testing days in order to investigate the test-retest reliability of background EEG, ERP and eye tracking measurements. The registration of EEG/ERP will be done using an electrode cap and the registration of eye movements with aid of a special camera. Furthermore, the interaction between the child and parent will be observed and cognitive development will be assessed. We strive to test all babies in the lab; but if parents indicate a preference for at-home testing, we can adapt to that request and visit them at home with the testing equipment.
To obtain estimates of the test-retest reliability, we will invite the children for the second, repeated measurement after maximally 2 weeks. We aim to perform the complete measurements twice in 35 babies. As in practice, between 50% and 67% of the measurements in infants succeeds (de Haan et al., 2009), we will include a gross total of 75 infants. We will stop the inclusions when we reach 35 successful measurements at both days.

Study burden and risks

This research is group-related because the study parameters are age-dependent. Test-retest values are likely to differ between infants and older children or adults.
There are no known risks associated with participation in the proposed research and the burden is estimated to be moderate: a total course of 1,5 days at the research center or 2 days at home, comprising approximately 180 minutes of

actual measuring time (twice 90 minutes). We emphasize that the actual measuring time and task burden for the baby is NOT 1,5 or 2 days, but approximately 90 minutes per testing day. We try to keep the burden for the child as low as possible by adapting to the natural day-rhythm of the child and leave ample time for rests and sleep. For that reason, we schedule a half to a full day for 90 minutes of actual measurement.
The low burden for infant and parents can be concluded from a small parent evaluation survey of a testing day.
An extensive evaluation of the burden experienced by parents and children in this type of testing day is included in this study.

Contacts

Public
Universiteit Utrecht

Heidelberglaan 1
Utrecht 3584CS
NL
Scientific
Universiteit Utrecht

Heidelberglaan 1
Utrecht 3584CS
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

• Age 10 months old (± 4 weeks; at time of testing)

• Born fullterm (>37)

Exclusion criteria

• Infant was premature (pre 37 weeks)
• Infant is looked after by the state (e.g. foster care), or other situation in which neither birth parent is involved in the infant*s care.
• Presence of known significant uncorrected vision or hearing impairment in infant (reported to parent by a doctor or health professional)
• Presence of known significant developmental or medical condition in infant likely to affect brain development or infant*s ability to participate in the study (e.g. Cerebral Palsy, Down*s syndrome, cystic fibrosis; reported to parent by a doctor or health professional)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-08-2014
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO

Date:	16-06-2014
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	02-07-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	03-11-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-09-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	16-01-2019
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	NL49099.041.14