The measurement of EEG in combination with auditive stimuli (ERP) and visual stimuli (eyetracking), and OCT to obtain reference values in healthy typically developing children (0-18 years).

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Our primary objective is to collect normative reference values in typically healthy developing children, aged 0 - 18 years, for EEG in combination with ERP and eyetracking, and OCT measurements (For details see also paragraph 5.1).

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

Summary

ID

NL-OMON57409

Source
ToetsingOnline

Brief title
SuperSEN study: Reference Values Project

Condition

- Other condition

Synonym
Healthy children

Health condition

Healthy children

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Reference values ChildBrainLab

Outcome measures

Primary outcome

The basic visual information processing tasks trigger reflexive responses.

Here, the main outcome measures are:

* Performance score (target seen/unseen)

* Reaction time to target fixation (milliseconds)

The more complex visual information processing tasks result in (complex) gaze patterns based on scanning of pictures or videos. A relationship is assumed between a person*s gaze and thoughts. Saccades, a short period in which we are unable to see, and fixations, a longer period in which we (re)direct our attention on specific visual features, are commonly used as outcome measures in eye tracking research. Here, the main outcome measures are:

* Performance scores (correct yes / no)

* Fixation duration (milliseconds) * Gaze sequence

* Number of visits to targets

EEG data will be screened.

Functional connectivity of EEG is a technique that is being adopted but there is not yet an established gold standard in the field (Nentwich 2020). Therefore, the start will be with the parameters phase lag index and coherence, and establish test-retest reliability in our set-up, starting with relaxed eye-closure.

For ERP the main study parameters will be amplitude and latency of the N1-P2-N2 peaks. The ERP recordings will be preprocessed (e.g., averaging, filtering) and analyzed using methods such as peak latency and amplitude measurements.

In OCT the total retinal thickness (TRT), the retinal nerve fiber layer thickness (RNFL) and the ganglion cell layer (GCL) thickness are the main study parameters and will be measured on the scan. The data processing is done by the principal investigator with an experienced ophthalmologist regarding OCT data. The total retinal thickness (TRT), ganglion cell layer thickness and the retinal nerve fiber layer (RNFL) obtained from the OCT will be expressed as mean ± standard deviation. A mean of all the nine areas of the ETDRS grid (circle and quadrants) will be calculated.

Secondary outcome

Not applicable

Study description

Background summary

The Pediatric Brain Center (PBC) is one of the four focus areas of the Erasmus MC Sophia Children*s Hospital. In the PBC several departments work together to care for children with conditions of the head/brain, senses, and limbs. Most of these patients have or are at risk of disabilities in cognition, behavior, communication, motor function and/or participation (in daily life, e.g. school) to a variable degree. This makes them vulnerable in society and we recognize that identifying risk factors for deviations in one or more domains may provide the opportunity to intervene as early as possible and support functioning in daily life. In the PBC several NFU (Dutch Federation of Academic Medical Centers) recognized national expertise centers are specifically aimed at multidisciplinary care-paths, combined with research. For other patient groups, there is not yet an expertise center they can benefit from. Preliminary research done by PBC members confirms that parents and caretakers worry about their child*s ability to grow into an independent adult. Our patients and parents tell us that they need attention to meaningful outcomes, emotional wellbeing, and burden of care (Heijdenrijk, 2021) In order to achieve relevant and meaningful outcomes, it will be necessary to compare test results to *what is normal". Currently, many pediatric tests cannot be appropriately interpreted because of using reference intervals derived from either adult population, hospitalized pediatric populations, or from outdated methodologies. Age-specific reference intervals are important for interpreting measurements in the pediatric population but unfortunately, there are very few studies that provide this information. In the CBL we measure the development of the participants in different relevant domains in three different rooms. These include psychological functions (intelligence, emotions, communication, and behavior) in the cognition room, motor function and growth in the motor room, and senses and neurophysiology in the sensory room. The SuperSEN study will be conducted in the sensory room. In the sensory room a multisensory measurement setup is created to simultaneously generate visual and auditory stimuli to measure the evoked brain activity using EEG, with respectively eye movement responses using EyeTracking and Evoked Related Potentials (ERP). Furthermore, a new EEG cap is being used to measure EEG. In contrast to the traditional use of separate electrodes, this cap could be less time consuming and more appropriate to use in children with or without head injuries. In addition, an Optical Coherence Tomography (OCT) device is present to make detailed retinal scans.

Study objective

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Study design

Prospective (cross sectional), single center.

Study burden and risks

The burden of participating in this project is a time investment, i.e. children must visit the CBL in Erasmus MC Sophia Children's Hospital for approximately one hour to perform measurements.
The tests are non-invasive and not painful. Children will for example be asked to do different information processing tasks, wear an EEG cap, and look into an OCT-machine.
Children, parents and/or caregivers will be informed that measurements are performed in a research setting. All data is collected for research purposes only and therefore individual results will not be shared with participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)
Babies and toddlers (28 days-23 months)

Inclusion criteria

Healthy children aged 0 - 18 years old

Exclusion criteria

* Receives treatment from a (para)medical professional for a neurological disorder.
* Receives treatment from a (para)medical professional for a psychiatric/mental health disorder.
* Injury or diagnosis that affect eyesight (high hyperopia (>=+4 D) or high myopia (<=*2.5 D).
* Injury or diagnosis that affect hearing. * Gestational age < 37 weeks or > 42 weeks

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	03-04-2025
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL88541.078.24