

Child Brain Lab Circuit

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Objectives: 1) Create shared and disease-specific developmental curves with relevant and meaningful outcomes in children with brain-related disorders. 2) Develop innovative paradigms and parameters from neurophysiological, brain structure and motor...

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

Summary

ID

NL-OMON53407

Source

ToetsingOnline

Brief title

CBL circuit

Condition

- Other condition

Synonym

brain related disorders

Health condition

hersengerelateerde aandoeningen

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: stichting vrienden van het Sophia

Intervention

Keyword: brain related disorders, cognitive and motor development, long term follow-up, neurophysiology

Outcome measures

Primary outcome

Main study parameters/endpoints: In the Child Brain Lab (CBL) we measure development of the participants on different relevant domains. These include psychological functions (intelligence, emotions, communication and behaviour), motor function, growth, senses and neurophysiology. Data will be analysed per disorder and cross-disorder. We aim at inviting participants for 5 repeated assessments between 0 and 18 years of age; in case a diagnosis is made at a later age this may be less, and in specific disorders subtest may be done more often. The design of the Self-Portrait and the effect on patient/family satisfaction, participation and shared decision making will be analysed

Secondary outcome

see primary

Study description

Background summary

Rationale: The Pediatric Brain Center (PBC) is a collaboration of medical professionals and researchers in the Sophia Children's Hospital that are involved in the clinical care for and research in children with conditions of the brain, nerves, senses and limbs. To improve patient and family participation, quality of care (now and in the future) and facilitate research and trials, we established the Child Brain Lab. The CBL is a function lab that will allow us to do standardized follow-up in relevant and meaningful domains.

Study objective

Objectives:

- 1) Create shared and disease-specific developmental curves with relevant and meaningful outcomes in children with brain-related disorders.
- 2) Develop innovative paradigms and parameters from neurophysiological, brain structure and motor measurements.
- 3) Use advanced data-analyses/statistical techniques and AI to identify early biomarkers that predict long term development
- 4) Boost patient engagement by embedding the data acquired in the Child Brain Lab in a life course and personalised-medicine framework for use in patient care and to support outcome-based care and shared decision-making (SDM) with the Self-Portrait.

Study design

Study design: Prospective cohort study

Study burden and risks

The burden of participating in the CBL test circuit is a time investment of 0.5 to 1 day, depending on the child's age and developmental level. The tests are non-invasive and not painful. Children will e.g. be asked to do different information processing tasks, wear an EEG cap, look into the OCT machine, and walk on an walkway with sensors. Details are found in paragraph 8. Benefit for the participating families is that they will get a concise version of the results of the tests of their child in a Self-Portrait, an application we will develop to support outcome-based healthcare and shared decision making. Families can use the Self-Portrait in the next consultation with their specialist to discuss the development of their child. If results give rise to concern, further treatment will be offered in the PBC or by referral to the appropriate professional. The CBL is inherently group related, both as we aim to improve patient care and participation of our patient group as to generate natural history data on our patient groups.

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)

Newborns

Inclusion criteria

Patients with disorders of brain, limbs and senses that are seen more than once at the outpatient clinic of the pediatric brain center, aged 0-18 years of age, able to return for long-term follow-up

Exclusion criteria

Patients who are unable to comply with the test circuit at the discretion of the treating physician

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 27-03-2023

Enrollment: 800

Type: Actual

Ethics review

Approved WMO

Date: 20-02-2023

Application type: First submission

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

Approved WMO

Date: 26-07-2023

Application type: Amendment

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

Approved WMO

Date: 11-02-2025

Application type: Amendment

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	NL82466.078.22