Database for Controls in Neuroscience Studies (D-CNS)

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

Summary

ID

NL-OMON52002

Source
ToetsingOnline

Brief title
D-CNS

Condition

- Other condition

Synonym
healthy development, typically developing

Health condition

gezonde ontwikkeling

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Cornelia stichting;JANIVO stichting;ZonMw.

Intervention

Keyword: controls, database, neuroscience, pediatrics

Outcome measures

Primary outcome

No primary end-point is defined for this study. Background characteristics involve demographics and medical history. Relevant outcome domains studied here involve neurophysiological, neurocognitive, behavioral and academic functioning.

- Demographics and medical history will be collected using a custom questionnaire developed by the Emma Neuroscience Group.
- Behavioural functioning of children and youth will be assessed using the extended version of the Strengths and Difficulties Questionnaire (SDQ) (Van Widenfelt, Goedhart, Treffers & Goodman, 2003). Besides the SDQ, the Strengths and Weaknesses of ADHD symptoms and Normal behaviour scale (SWAN; Swanson et al., 2012) will be used to assess behavioural functioning.
- Cognitive functioning will be assessed using a version of the Wechsler Intelligence Scale (depending on the participants age) (Wechsler, 2002; Wechsler, 2005; Wechsler, 2008).
- Neurocognitive functions will be assessed using the Emma Toolbox for Computerized Neurocognitive Testing. The Emma Toolbox is an in-house designed

battery of computerized tests, presented as games, that assesses neurocognitive domains (e.g. information processing, attention, learning & memory, and visuomotor integration).

- Brain activity will be measured using EEG, a non-invasive and widely used tool to assess the E-I balance.

- School performance: CITO Pupil Monitoring System results will be used to assess school performance.

Secondary outcome

not applicable

Study description

Background summary

Control data of typically developing (TD) children is required to investigate the nature and manifestation of pediatric conditions. At present every pediatric population of interest is compared to a newly recruited control group. This inefficient way of working may be served by formation of a database including control data on a wide range of domains that will act as a universal control group in future pediatric projects. Such a database may also allow studying relations between different domains of functioning in TD children and to better understand their manifestation in clinical populations.

Study objective

The current study aims to establish a database containing control data of TD children on a range of relevant domains for clinical neuroscientific research, including data on demographics, medical history, as well as neurophysiological, behavioural, neurocognitive and academic functioning. The database can be used as a universal control group in future studies in the field of pediatric neuroscience. In addition, we aim to study the relations between different domains of functioning in TD children across development to better understand the relationship between the studied domains of functioning.

Study design

Observational study.

Study burden and risks

Participation in this study consists of one test session, with an estimated duration of 3 hours. The test session consists of (parent and child rated) questionnaires, electroencephalogram (EEG) assessment and neurocognitive assessment. Dependent on the explicit informed consent from the legal guardian(s), pupil monitoring system (CITO) data will be collected as a measure of academic performance. The resulting database will function as a universal control group in future paediatric projects. Currently identified projects are on pediatrics who experienced Traumatic Brain Injury and children that are diagnosed with Autism Spectrum Disorder. Such projects will be presented for ethical review separately. The control database is necessary to elucidate the impact of specified disorders on the identified outcome measures, as corrected for a range of background variables (e.g. demographics and medical history). Standardized population norms are available for some of the outcome measures, but these norms are only standardized for age and/or sex, while it is well-known that other demographic characteristics can have a considerable influence on paediatric functioning (i.e. socio-economic status). The confounding influence of the complex interplay between numerous variables needs to be taken into account for valid and reliable research in paediatric cohorts. By creating this control database we will reduce the burden for multiple future projects that require a control group, hence minimizing the total burden exercised by our research on TD children and their parents.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

1. 4-18 years old;
2. Fluent Dutch speaker;
3. Inhabitant of the Netherlands.

Exclusion criteria

1. Absence or withdrawal of written informed consent;
2. Severe motor disability that interferes with outcome assessment;
3. Inability to comprehend testing instructions.

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):	09-07-2021
Enrollment:	210
Type:	Actual

Ethics review

Approved WMO Date:	04-06-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-03-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 25801
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL76915.018.21
OMON	NL-OMON25801