Imaging Human Cognition

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

Summary

ID

NL-OMON55541

Source
ToetsingOnline

Brief title
Imaging Human Cognition

Condition

- Other condition

Synonym
brain research, human cognition

Health condition

exploratief neurowetenschappelijk onderzoek

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: Ministerie van OC&W,NWO,Europese Unie;collectebusfondsen

Intervention

Keyword: Behavioral research, Cognitive Neuroscience, Electrophysiology, Neuroimaging

Outcome measures

Primary outcome

(f)MRI, MEG, EEG, fNIRS, behavioural research through neuropsychological tasks, questionnaires, behavioural or neuroimaging parameters in relation to t(A/D)CS.

Secondary outcome

Electrodermal activity (EDA), heart rate, breathing rate, eye-tracking, surface electromyography (EMG), blood pressure, hormone levels assessed from saliva and/or urine samples, questionnaires, BMI, online testing, experience sampling/ecological momentary assessment through a smartphone or wearables, relevant participant characteristics such as age, handedness, colour blindness, hearing problems, (native) language, education level and other relevant demographic information necessary for the study.

Study description

Background summary

The Donders Centre for Cognitive Neuroimaging (DCCN) conducts basic and applied research in cognitive neuroscience. Much of the recent rapid progress in this field is driven by the development of complex neuro-imaging techniques for the in-vivo scanning of activity in the human brain, an area in which the DCCN plays a leading role.

Research at the DCCN focuses on central cognitive functions. The aim is to unravel these complex functions and understand how they are represented in the brain. This is done by identifying the networks of brain areas that are vital to each of these functions and determining the role of - and interactions between - regions. In order to achieve this, it is also necessary to understand how neurons make networks and how networks carry out cognitive functions, in

other words, how to get from neurons to cognition. Research at the centre is also designed to establish how the different brain areas coordinate their activity with very high temporal accuracy in order to enable human cognition.

Study objective

At the brain system level, we seek to investigate whether neural response patterns obtained by fMRI, MEG EEG, t(A/D)CS and fNIRS can reveal the neural and physiological mechanism behind cognitive processes in general, more specifically per study addressing the study-specific rationale and questions. Most of the scan techniques are combined with social/psychological behavioural questionnaires or tests with additional neuro-psycho-physiological measures in order to answer secondary questions.

Study design

On annual basis roughly 40 new studies are conducted with different research questions, rationale and design which use the available neuroimaging methods at the DCCN: (f)MRI, MEG, EEG, fNIRS and t(A/D)CS. All studies go through a strict approval process and checks before researchers can book the labs and recruit and test participants. These procedures are monitored by the relevant support staff, e.g., a research coordinator, data steward, privacy officer, and lab managers. Studies are also randomly monitored throughout the year to check protocol compliancy, participant safety and rights, and data management and quality. Participant recruitment happens mostly through SONA: a safe and commonly used system on campus. The informed consent procedure is documented in a standard operating procedure (SOP) and the use of Castor and following the DCCN's data management plans is mandatory for all studies conducted under this blanket protocol.

Study burden and risks

The risk and burden associated with participation can be considered as neglible. No pharmacological or (otherwise) invasive interventions are applied.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Competent adolescents and adult volunteers (>=16 years of age)
Normal or to normal corrected vision
Normal-uncorrected hearing
Willingness and ability to understand nature and content of the study and give informed consent
Ability to participate and comply to study requirements

Exclusion criteria

History of or current neurological treatment
Current psychiatric diagnosis and/or treatment
History of or current brain surgery or epilepsy
Pregnancy
Method-specific exclusion criteria. For an MRI study this is e.g., metal in the upper body and claustrophobia. These are further specified in the method-specific screening forms

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-09-2014
Enrollment:	15000
Type:	Actual

Ethics review

Approved WMO Date:	27-08-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-11-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-11-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-12-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-01-2015

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-01-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-02-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-10-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-01-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-04-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-05-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-12-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-01-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-02-2021

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-04-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-03-2024
Application type:	Amendment
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	NL45659.091.14