Neurocognitive development of decision-making

Published: 31-10-2007
Last updated: 08-05-2024

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

Summary

ID

NL-OMON30953

Source
ToetsingOnline

Brief title
NCDM2

Condition

- Other condition

Synonym
nvt

Health condition

nvt. het betreft onderzoek naar gezonde ontwikkeling

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: decision-making, development, fMRI

Outcome measures

Primary outcome

fMRI data and behavioral responses related to decision making

Secondary outcome

Autonimic measures and questionnaire data

Study description

Background summary

Neuropsychological and neuroimaging studies in adults have suggested that two important components of decision-making, stimulus anticipation and feedback processing associated with social and non-social processes, rely on separable regions within the prefrontal cortex (PFC). Behavioral and psychophysiological studies have shown that there are large developmental changes in these putative functions. This study has the goal to understand functional brain maturation that subserves developmental change in stimulus anticipation and outcome processing in a social and non-social decision-making task.

Study objective

The main objective is to examine the development of brain regions that are known to be important for social and non-social decision-making in adults, and to examine whether there are different developmental trajectories for these brain regions that underlie changes in behaviour from late childhood into adulthood.

Study design

This study uses an experimental design. Participants will perform a computerized decision-making task under easy and difficult conditions, and we

will measure brain activation using functional Magnetic Resonance Imaging (fMRI) and autonomic responses while they are performing the task.

Study burden and risks

There are no known risks associated with participating in an fMRI study. This is a noninvasive technique involving no catheterizations or introduction of exogenous tracers. Numerous children and adults have undergone magnetic resonance studies without apparent harmful consequences. Some people become claustrophobic while inside the magnet and in these cases the study will be terminated immediately at the subject's request. The only absolute contraindications to MRI studies are the presence of intracranial or intraocular metal, or a pacemaker. Relative contraindications include pregnancy and claustrophobia. Subjects who may be pregnant, who may have metallic foreign bodies in the eyes or head, or who have cardiac pacemakers will be excluded because of potential contraindications of MRI in such subjects. Although there is no direct benefit to the participants from this proposed research, there are greater benefits to society from the potential knowledge gained from this study. This knowledge about normal development is critical to aid in the understanding of cases of abnormal development, as seen in children with schizophrenia, Attention Deficit Hyperactivity Disorder, Obsessive-Compulsive Disorder,
Tourette*s syndrome, or traumatic brain injury.

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)
Elderly (65 years and older)

Inclusion criteria

Children, adolescents and adults in the ageranges mentioned at D3 with no history of neurological disorders or contra-indications for MRI will be included in the study.

Exclusion criteria

Contra-indications to MRI and Claustrophobia

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):	01-11-2007
Enrollment:	100

Type:	Anticipated

Ethics review

Approved WMO Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL18739.058.07