Neurocognitive Development of Reading Comprehension

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The main objective of this proposal is to request permission for recruitment and participation of individuals between ages 8 and 30 in an fMRI session and several behavioral testing sessions. These studies are aimed at relating brain development to...

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

Summary

ID

NL-OMON37336

Source
ToetsingOnline

Brief title
fMRI of Reading Comprehension Development

Condition

- Other condition

Synonym
n/a

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: Development, fMRI, Reading

Outcome measures

Primary outcome

N/A

Secondary outcome

N/A

Study description

Background summary

In the last decade the advancement of neuroimaging methods has given us important insights in changes in brain structure and function in late childhood, adolescence and adulthood. The proposed study is aimed at examining the development of reading comprehension and associated cognitive control functions in relation to structural and functional brain development between the ages of 8 and 30 years of age. In addition, it will enable the investigation of individual differences in developmental trajectories and allow for a better understanding of problems in the acquisition of reading comprehension skills.

Study objective

The main objective of this proposal is to request permission for recruitment and participation of individuals between ages 8 and 30 in an fMRI session and several behavioral testing sessions. These studies are aimed at relating brain development to cognitive development in childhood, adolescence and early adulthood.

Study design

The study uses an experimental design. Participants will perform age

appropriate computerized cognitive tasks. We will measure brain activation using functional Magnetic Resonance Imaging (fMRI) while participants are performing these tasks and during rest. We will use structural MRI and Diffusion Tensor Imaging (DTI) to measure underlying brain anatomical processes. In addition, we will measure cognitive functioning on a battery of tasks outside of the scanner. All measurements are non-invasive and age appropriate.

Study burden and risks

There are no known risks associated with participating in an MRI 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. Volunteers might experience discomfort because of the scanner sounds or claustrophobia while inside the magnet. 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 metal in the body. Relative contraindications include pregnancy and claustrophobia. Participants who may be pregnant, who may have metallic foreign bodies in the eyes, head or body, or who have cardiac pacemakers will not be included in the study. 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. Understanding of the processes involved in higher order reading processes such as reading comprehension, and the possible sources of difficulties has direct and far-reaching implications for instructional practice, including diagnosis, prevention, and remediation.

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 and adults between the ages of 8 and 30 years old with no history of neurological disorder/disease and no counter-indications to MRI will be included in this study. All participants will be right-handed, with normal or corrected to normal vision.

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:	Recruitment stopped
Start date (anticipated):	16-10-2011
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	18-06-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL40315.058.12