The Neurobiological Foundations of Treatment Response in Children with Developmental Dyslexia: An exploratory study

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

Summary

ID

NL-OMON42443

Source
ToetsingOnline

Brief title
Dyslexia treatment

Condition

- Other condition

Synonym
Dyslexia; Reading Disorder

Health condition

Leerstoornis

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Developmental dyslexia, Response to treatment

Outcome measures

Primary outcome

In the proposed study, brain activation patterns and structural measures of the connectivity of the brain are the dependent variables. We are particularly interested in the neural correlates of treatment response and whether and how this resembles or differs from age- and reading matched controls.

Secondary outcome

On a behavioural level, we will measure reading accuracy and fluency, phonological awareness capacity, and response to online altered auditory feedback (as a measure of speech perception/production interactions).

Study description

Background summary

Developmental Dyslexia (DD) is a brain-based difficulty in acquiring fluent word decoding skills, and despite much effort to detect and treat DD as early as possible, 20-40% of the children diagnosed with DD continue to lack decent reading abilities after treatment. The behavioural and neural origins of the response to treatment are underinvestigated and poorly understood. This study employs an integrated brain-behaviour design to examine whether and how responsiveness to treatment depends on the structural and functional brain organization.

Study objective

We aim to identify neurobiological correlates of treatment response in children with DD and will examine how phonological and speech abilities are related to brain measures in children with DD as well as in controls. As a secondary objective, we want to investigate how these relations differ for different orthographies.

Study design

Structural and functional brain scans will be obtained from children with DD with varying levels of responsiveness to treatment, and age- and reading matched controls. Behavioural measures of reading, phonological and speech abilities will be administered to use as covariates/regressors in the analyses. Total time of participation from entrance till departure approximates 2 hours.

Study burden and risks

As reading is eminently an ability acquired in childhood, this study involves children. There are no risks associated with participation in this study. Several precautions are made to minimize any potential discomfort.

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)

Inclusion criteria

Dyslexic children
- 11-13 years of age
- Children with dyslexia must have completed a DD treatment program according to the Dutch nationally standardized protocol (see Blomert, 2006)
- Speak Dutch as their first language
Control group
- 11-13 years of age or
- 8-10 years of age
- No diagnosis of dyslexia
- Speak Dutch as their first language

Exclusion criteria

- The participant has developmental dyslexia, but has not (yet) finished a DD treatment program.
- Significant hearing or visual impairments not correctable by glasses or hearing aids
- Any MRI counter-indications (e.g., metal implants, braces)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2016
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO

Date:	05-01-2016
Application type:	First submission
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	NL55093.091.15

Study results

Date completed:	04-11-2016
Actual enrolment:	41