ISRCTN12783279 https://doi.org/10.1186/ISRCTN12783279

Training letter-speech sound associations to improve reading fluency in children with dyslexia

Submission date
12/02/2015

Recruitment status
No longer recruiting

Registration date
26/02/2015

Overall study status
Completed

Last Edited
08/03/2023

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Dyslexia is a developmental disorder of reading heavily impacting the academic and economic opportunities of the affected individuals. The most characteristic and persistent symptom is a lack of fluency in reading. The results of interventions for dyslexia show clear improvements in reading accuracy, but hardly in reading fluency. Recent neurocognitive research suggests that a failure to develop automatic letter-sound associations results in an impairment of reading fluency in dyslexia. The aim of the present study is to examine whether an intervention intensively training these letter-speech sound associations is able to improve fluent reading in children with dyslexia.

Who can participate?
Children between 8 and 9 years of age, diagnosed with severe dyslexia.

What does the study involve?
After initial assessment, a total of 50 children with dyslexia are randomly allocated to one of two groups: an intensive intervention group (intervention) or a waiting list group (control). Participants that are allocated to the waiting list group will receive the intervention after the waiting period has elapsed. In addition, a second control group of normal readers (not receiving intervention) is included in the study, in order to compare the reading growth of the children with dyslexia with those of normal readers during the intervention period. The training program is provided by well-instructed junior psychologists, on a one-to-one basis for 45-minute sessions during a 19 week period. The training frequency is two sessions per week. Reading and reading-related measures at both behavioural and brain (EEG) level are administered before and after the intervention period.

What are the possible benefits and risks of participating?
We expect that the intervention will improve reading fluency. The study does not involve any danger for the participants, and any participants who are allocated to the control group will have the opportunity to participate in the training program after the end of the study period.

Where is the study run from?
The lead center is the Rudolf Berlin Center for learning disabilities, University of Amsterdam, the Netherlands. Additionally, the centres of the IWAL Institute in Amsterdam, Haarlem, and Zaandam in the Netherlands are included.

When is the study starting and how long is it expected to run for?
January 2012 to October 2012.

Who is funding the study?
National Initiative Brain and Cognition of the Netherlands Organization for Scientific Research (NWO)

Who is the main contact?
Dr Jurgen Tijms
j.tijms@uva.nl

Contact information

Type(s)
Scientific

Contact name
Dr Jurgen Tijms

Contact details
Rudolf Berlin Center
University of Amsterdam
Valckenierstraat 65-67
Amsterdam
Netherlands
1018XE
+31-20-2233970
j.tijms@uva.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HCMI 056-14-015

Study information

Scientific Title
A randomised controlled trial of a computerised intervention addressing letter-speech sound integration in order to improve reading fluency in children with severe dyslexia

Study objectives
The study aims to determine whether a computer-based intervention focussed on intensively training automation of letter-speech-sound associations can improve reading fluency in children with severe dyslexia. The primary hypothesis is that the intervention group will have improved more in reading fluency during the intervention period than the wait-list group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Psychology Department of the University of Amsterdam, 06/12/2011, ref: 2011-OP-1907.

Study design
Interventional open randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Mental Health; Subtopic: Learning Disorder; Disease: Severe Dyslexia

Interventions
A single-centre trial of a cognitive intervention compared to wait-list control.
The intervention in this study is a computerised intervention addressing the integration of letters and speech sounds in the context of the acquisition of reading fluency. The intervention program is delivered by well-instructed junior psychologists, on a one-to-one basis for 45-minute sessions during a 19 week period. The training frequency is two sessions per week. Intervention takes place at a clinical centre.

Children with severe dyslexia are randomly assigned to one of the following two conditions:
1. An immediate intervention group,
2. A waiting-list control group.

In addition, a second control group of normal readers (not receiving the intervention; same age-range, school grade, sociodemographical background, and exclusion criteria as the children with dyslexia) is included in the study, in order to compare the reading growth curves of the children with dyslexia with those of normal readers during the intervention period.

Intervention Type
Behavioural

Primary outcome measure
1. Reading Accuracy (3DM, Blomert & Vaessen, 2009)
2. Reading Fluency (3DM, Blomert & Vaessen, 2009)
Primary measures are measured at baseline and at the end of the intervention (after 19 weeks).

Secondary outcome measures
1. Letter-speech sound identification - Accuracy (3DM, Blomert & Vaessen, 2009)
2. Letter-speech sound identification - Fluency (3DM, Blomert & Vaessen, 2009)
3. Letter-speech sound discrimination - Accuracy (3DM, Blomert & Vaessen, 2009)
4. Letter-speech sound discrimination - Fluency (3DM, Blomert & Vaessen, 2009)
5. Spelling - Accuracy (3DM, Blomert & Vaessen, 2009)
6. Spelling - Fluency (3DM, Blomert & Vaessen, 2009)
7. Word reading fluency (EMT, Brus & Voeten, 1999)
8. Text reading fluency (SVT-TL, De Vos, 2007)
9. ERP (Event-Related Potential), audiovisual MMN of letter-speech sound pairs
10. ERP, visual word recognition

Secondary measures number 1 to 8 are measured at baseline and at the end of the intervention (after 19 weeks). The two ERP-measures (number 9 and 10) are measured at baseline and at the end of the intervention (after 19 weeks) for the intervention group, and only once, at approximately 10 weeks, for both the waiting-list control group and the normal-reader control group (used as a criterion point to compare the pre-post ERP-changes in the intervention with).

Overall study start date
01/09/2011

Completion date
01/10/2012

Eligibility

Key inclusion criteria
1. Diagnosis of dyslexia (according to criteria of Dutch Dyslexia Foundation, and DSM-IV-TR / reading disorder)
2. Suffering from specific and persistent (i.e., failed to respond to remedial support at school) problems with reading acquisition at school
3. Percentile score of 10 or lower on a standard reading test
4. Aged 8 to 9 years old
5. In grade 3 of primary education

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
9 Years

Sex
Both

Target number of participants
Planned sample size: N = 50 children with severe dyslexia; subjects fulfilling the entry criteria will be randomised to one of the two trial arms. N=25 normal reading children.

Total final enrolment
67

Key exclusion criteria
1. Behavioral and/or attention disorders (as measured by the Child Behavior Checklist (CBCL)
2. IQ < 85
3. Uncorrected sight problems
4. Hearing loss

Date of first enrolment
01/10/2011

Date of final enrolment
23/12/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
Rudolf Berlin Center
Valckenierstraat 65-67
Amsterdam
Netherlands
1018XE

Study participating centre
IWAL Institute
Prins Hendrikkade 84

Amsterdam
Netherlands
1012AE

Sponsor information

Organisation
University of Amsterdam

Sponsor details
Weesperplein 4
Amsterdam
Netherlands
1018XA

Sponsor type
University/education

Website
www.uva.nl

ROR
https://ror.org/04dkp9463

Funder(s)

Funder type
Research organisation

Funder Name
National Initiative Brain and Cognition of the Netherlands Organization for Scientific Research (NWO)

Results and Publications

Publication and dissemination plan
We plan to publish our results in the second half of 2015

Intention to publish date
31/12/2015

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/12/2015		Yes	No
Protocol (other)		02/12/2015	08/03/2023	No	No