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Prismatic adaptation for the treatment of dyslexia

Submission date
20/10/2023

Recruitment status
No longer recruiting

Registration date
21/11/2023

Overall study status
Completed

Last Edited
28/01/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Developmental dyslexia (DD) is a neurodevelopmental disorder characterized by poor reading acquisition, despite adequate intelligence and sensory-motor skills. DD occurs in 5–10% of the population and may limit academic and professional achievement. Current treatment options for dyslexia show modest effectiveness, are often time-consuming, and are scarcely appealing to children and adolescents. The aim of this study is to evaluate a rehabilitation technique, prismatic adaptation (PA), as a new treatment for DD.

Who can participate?
Adolescents aged 13-17 years diagnosed with DD at the specialty learning disability clinic of Sapienza University of Rome, Italy.

What does the study involve?
Participants will be randomly assigned to one of two groups, intervention or waitlist. All participants in the waitlist group will be informed at baseline that they will be offered the intervention at follow-up, i.e., after 10 weeks.
The intervention group participates in sessions of PA combined with a digital intervention for the training of memory and attention by means of the MindLenses (TM) device. PA is a non-invasive technique that consists in wearing special goggles with prismatic lenses while pointing to a target. This enables a recalibration of visual attention after a few minutes of pointing. Treatment sessions will be held once weekly for 10 consecutive weeks and last about 30 minutes. At the end of the treatment period and at 6, and 10 months after treatment end, participants will be revaluated by our research team to assess treatment benefits.

What are the possible benefits and risks of participating?
There are no potential harms known from the use of PA although potential tiredness due to treatment length (once-weekly sessions over 10 consecutive weeks) cannot be excluded.

Where is the study run from?
Sapienza University of Rome (Italy)

When is the study starting and how long is it expected to run for?
December 2021 to October 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Lauro Quadrana, lauro.quadrana@uniroma1.it

Contact information

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Prismatic adaptation coupled with cognitive training: a novel non-phonological treatment for developmental dyslexia

Acronym
PA for dyslexia

Study objectives
Prismatic adaptation combined with cognitive training improves reading abilities in adolescents with developmental dyslexia

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/01/2024, Comitato Etico Lazio Area 1 (Viale del Policlinico 155, Rome, 00161, Italy; +39 (0)3280057979; giulia.conte@uniroma1.it), ref: 0195/2024

Study design
Interventional non-pharmacological randomized controlled with cross-over phase

Primary study design
Interventional

Study type(s)
Efficacy, Treatment

Health condition(s) or problem(s) studied
Developmental dyslexia

Interventions

Prismatic adaptation, i.e., a visuomotor adaptation technique, combined with cognitive training will be delivered by means of the MindLenses (TM) device to study participants in order to evaluate the efficacy of treatment for dyslexia remediation.

Recruited participants will be randomly assigned to one of two groups, intervention or waitlist. All participants assigned to the intervention arm will receive 10 sessions of PA combined with tablet-delivered cognitive training delivered once weekly. All participants in the waitlist group will be informed at baseline that they will be offered the intervention at follow-up, i.e., after 10 weeks. Two follow-up tests will be performed after treatment at 6 months and at 12 months, to provide information on the duration of treatment effects over time.

The researchers used a stratified randomization method to control and balance the influence of covariates. Sex (two levels: male, female) and age (two levels: 13.0-14.9 years, 15.0-16.9 years) were used to achieve balance among groups in terms of participants' baseline characteristics (covariates). With these two covariates, possible block combinations total four (e.g., female in the 13.0-14.9 age range). A simple randomization procedure, such as flipping a coin, is used to assign the participants within each block to one of the two treatment groups.

Intervention Type
Other

Primary outcome(s)
1. Reading speed, assessed in syllables per second and calculated using this formula (syllables read correctly/seconds) by reading out loud the text included in the MT-Avanzate-3 battery or the in the MT-16-19 battery. Assessed at baseline, 10 weeks after treatment start, 6 months after treatment end, 12 months after treatment end.
2. Reading accuracy, expressed as percentage value (%) of correct words and pseudowords read out loud from the DDE-2 battery. Assessed at baseline, 10 weeks after treatment start, 6 months after treatment end, 12 months after treatment end.

Key secondary outcome(s))
1. Working memory index, assessed as quotient (mean=100, 1 SD=15) provided by the Wechsler Intelligence Scale for Children - Fourth Edition. Assessed at baseline, 10 weeks after treatment start, 6 months after treatment end, 12 months after treatment end.
2. Processing speed index, assessed as quotient (mean=100, 1 SD=15) provided by the Wechsler Intelligence Scale for Children - Fourth Edition. Assessed at baseline, 10 weeks after treatment start, 6 months after treatment end, 12 months after treatment end.

Completion date
01/10/2024

Eligibility

Key inclusion criteria
1. Diagnosis of developmental dyslexia
2. Total IQ above the low average range (≥80), as confirmed on the Wechsler intelligence scale for children – fourth edition (WISC-IV)
3. Either Working Memory Index (WMI) or Processing Speed Index (PSI) below the low average range (80), or both

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
13 years

Upper age limit
17 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Presence of other neurodevelopmental disorders, particularly attention-deficit/hyperactivity disorder (ADHD)
2. Any major comorbid psychiatric disorder such as schizophrenia, bipolar disorder, or major depression disorder
a diagnosis of active epilepsy
3. Physical disabilities that could impair the use of the study instruments

Date of first enrolment
01/06/2022

Date of final enrolment
01/06/2024

Locations

Countries of recruitment
Italy

Study participating centre
Child & Adolescent Neuropsychiatry Institute, Policlinico Umberto I
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Sponsor information

Organisation
Policlinico Umberto I

ROR
https://ror.org/011cabk38

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets created and analysed for the current study will be made available upon request from Dr Lauro Quadrana (lauro.quadrana@uniroma1.it).
The type of data that will be shared: anonymous aggregate (group) data of the investigated outcome measures.
Dates of availability: after publication in a scientific journal.
Whether consent from participants was required and obtained: consent was required and obtained to participate in the study, which also implied the possibility of sharing participants' anonymized data for research publication and purposes only.
Comments on data anonymization: all data will be available upon reasonable request in aggregate form and completely anonymized.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/01/2026	28/01/2026	Yes	No