

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Aug 2026

Effectiveness of simultaneous dual-site transcranial direct current stimulation combined with integrated phonological and fine motor intervention compared with single interventions and sham in improving reading and phonological processing in 9-year-old boys with developmental dyslexia: a randomized, double-blind, sham-controlled trial

Protocol summary

Study aim

To evaluate the effectiveness of simultaneous dual-site transcranial direct current stimulation (tDCS) combined with integrated phonological and fine motor intervention, versus single interventions and sham, on reading and phonological processing in 9-year-old boys with developmental dyslexia.

Design

Randomized, double-blind, sham-controlled, 8-group component trial. Sample size: 160 (20 per group). Block randomization with block size 8 using a web-based sequence. Four assessment points: baseline, post-test, 3-month follow-up, 6-month follow-up.

Settings and conduct

Will be conducted in learning disorder clinics in Isfahan, Iran. Participants, parents, outcome assessors, therapists, and data analysts will be blinded; the tDCS operator will be unblinded. Topical benzocaine 6% will be applied before electrode placement to improve blinding.

Participants/Inclusion and exclusion criteria

Inclusion: 9-year-old boys with developmental dyslexia; NAMA T-score ≤ 30 ; Full Scale IQ ≥ 85 ; SCAS score < 88 ; BOT-2 standard score ≤ 40 ; normal or corrected sensory function; no tDCS contraindications; written consent and verbal assent. Exclusion: intellectual disability; epilepsy; metal implants; scalp lesions; uncorrected sensory deficits; other major psychiatric or neurodevelopmental disorders requiring ongoing treatment.

Intervention groups

Eight groups: control plus sham; sham with phonological training; sham with non-targeted motor training; sham with combined intervention; active tDCS reading network plus phonological; active tDCS motor cortex plus motor;

active dual-site tDCS plus combined; active tDCS motor cortex alone. tDCS: 1 mA, 20 min, 20 sessions.

Main outcome variables

Primary: change in composite NAMA Factor 1 score (word reading, phoneme deletion, nonword reading, word comprehension). Secondary: BOT-2 fine motor performance, rapid automatized naming, and text reading fluency.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260817070696N1**

Registration date: **2026-08-20, 1405/05/29**

Registration timing: **prospective**

Last update: **2026-08-20, 1405/05/29**

Update count: **0**

Registration date

2026-08-20, 1405/05/29

Registrant information

Name

Mohammad Amin Javedanfar

Name of organization / entity

Shahid Beheshti University

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Recruitment status

recruiting

Funding source**Expected recruitment start date**

2026-08-23, 1405/06/01

Expected recruitment end date

2027-02-18, 1405/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of simultaneous dual-site transcranial direct current stimulation combined with integrated phonological and fine motor intervention compared with single interventions and sham in improving reading and phonological processing in 9-year-old boys with developmental dyslexia: a randomized, double-blind, sham-controlled trial

Public title

Brain stimulation with combined reading and motor training for children with dyslexia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Male children aged 9 years (9 years 0 months to 9 years 11 months) with developmental dyslexia diagnosed according to DSM-5 criteria by a clinical team. Reading and Dyslexia Test (NAMA) T score ≤ 30 (at least 2 standard deviations below the mean). Full Scale IQ ≥ 85 on the Wechsler Intelligence Scale for Children, Fifth Edition (WISC-V). Score below 88 on the Spence Children's Anxiety Scale (SCAS). Fine motor deficits defined as standard score ≤ 40 on Bruininks-Oseretsky Test of Motor Proficiency, Second Edition (BOT-2) manual dexterity and upper-limb coordination subtests. Normal or corrected-to-normal vision and hearing. No history of seizure or epilepsy, no scalp skin disease, no cochlear implant, cardiac pacemaker, or metal implants in the skull. Written informed consent from parents or legal guardian and verbal assent from the child.

Exclusion criteria:

Intellectual disability (Full Scale IQ < 85). Personal history of epilepsy or seizure disorder, or epilepsy in a first-degree relative. Presence of cochlear implant, cardiac pacemaker, or metal implants in the skull. Skin diseases or open lesions on the scalp at electrode sites. Uncorrected visual or hearing impairments. Other primary psychiatric or neurodevelopmental disorders requiring ongoing treatment (e.g., ADHD, autism spectrum disorder, severe anxiety disorder).

Age

From **108 months** old to **119 months** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed using block randomization with a block size of 8. The unit of randomization will be the individual participant. A web-based random sequence generator (www.randomlists.com) will be used to create the allocation sequence. No stratification factors will be applied. Allocation concealment will be ensured by placing the allocation sequence in sequentially numbered, sealed, opaque envelopes. An independent research assistant who will not be involved in outcome assessment or intervention delivery will open the envelope at the time of each participant's enrollment and will assign the participant to the corresponding group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and their parents will be blinded to whether they receive active or sham tDCS. Outcome assessors and therapists delivering cognitive interventions will also be blinded. The tDCS operator will be the only unblinded person and will have no role in outcome assessment or cognitive training. Data analysts will be blinded to group labels until the primary analyses are completed. To reduce the initial tingling sensation and improve blinding, a topical local anesthetic (6% benzocaine) will be applied before electrode placement. A Data Safety and Monitoring Board (DSMB) will be unblinded as needed for safety monitoring.

Placebo

Used

Assignment

Parallel

Other design features

This will be an 8-group, theory-driven component trial (not a complete factorial design). The tDCS montage will be yoked to the type of cognitive intervention: TPJ stimulation for phonological training, M1 stimulation for motor training, and dual-site stimulation for the combined intervention. The combined intervention group will receive simultaneous two-channel tDCS and online cognitive training. A tDCS-only group (M1 montage) will be included to isolate the effect of motor cortex stimulation. Four assessment time points will be used: baseline, post-test, 3-month follow-up, and 6-month follow-up.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Shahid Beheshti University
Street address
Shahid Beheshti University, Shahid Shahriari Square, Evin, Tehran, Iran
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Province
Tehran
Postal code
1983969411
Approval date
2024-07-06, 1403/04/16
Ethics committee reference number
IR.SBU.REC.1403.103

Health conditions studied

1

Description of health condition studied
Developmental dyslexia
ICD-10 code
F81.0
ICD-10 code description
Specific reading disorder

Primary outcomes

1

Description
Composite score of Factor 1 of the Reading and Dyslexia Test, which includes word reading, phoneme deletion, nonword reading, and word comprehension subtests.
Timepoint
Before intervention, immediately after the end of intervention, 3 months after intervention, and 6 months after intervention.
Method of measurement
Reading and Dyslexia Test (a standardized Persian test for reading and dyslexia). The composite score of Factor 1 is calculated from the word reading, phoneme deletion, nonword reading, and word comprehension subtests.

Secondary outcomes

1

Description
Fine motor performance as measured by the Bruininks-Oseretsky Test of Motor Proficiency, Second Edition,

manual dexterity and upper-limb coordination subtests.

Timepoint
Before intervention, immediately after the end of intervention, 3 months after intervention, and 6 months after intervention.
Method of measurement
Bruininks-Oseretsky Test of Motor Proficiency, Second Edition. Raw scores of the common items in the manual dexterity and upper-limb coordination subtests will be used for longitudinal comparison.

2

Description
Rapid automatized naming speed, including naming of objects, colors, numbers, and letters.
Timepoint
Before intervention, immediately after the end of intervention, 3 months after intervention, and 6 months after intervention.
Method of measurement
Rapid Automatized Naming Test. The total time in seconds to name each card is recorded for the four subtests: objects, colors, numbers, and letters.

3

Description
Text reading fluency defined as the number of correct words read per minute on a grade-level reading passage.
Timepoint
Before intervention, immediately after the end of intervention, 3 months after intervention, and 6 months after intervention.
Method of measurement
Reading aloud a 100-word passage selected from the third-grade Persian textbook. Correct words per minute will be calculated as the total number of words minus errors, multiplied by 60, divided by the total reading time in seconds.

Intervention groups

1

Description
Control group: Participants will receive usual school education plus sham transcranial direct current stimulation. The sham stimulation will use the same electrode positions as the active groups, but the current will be applied for only 30 seconds and then gradually ramped down. For the control group, the sham montage will be randomly selected from the three main montages and will remain fixed across all 20 sessions. Sessions will be conducted three times per week for approximately seven weeks.
Category
Placebo

2

Description
Intervention group 1: sham transcranial direct current

stimulation with the anode over the left temporoparietal junction and the cathode over the right temporoparietal junction, plus phonological awareness training. Sham stimulation will be applied for only 30 seconds. Phonological awareness training will be delivered in 20 sessions of 60 minutes each, three times per week for about 7 weeks, and will cover syllable segmentation, rhyme, phoneme blending and segmentation, initial and final phoneme identification, phoneme manipulation, and grapheme-to-phoneme mapping.

Category

Behavior

3

Description

Intervention group 2: sham transcranial direct current stimulation with the anode over the left primary motor cortex and the cathode over the right supraorbital region, plus non-targeted fine motor training. Sham stimulation will be applied for only 30 seconds. Non-targeted fine motor training will include activities without linguistic content, such as free play with dough, bead threading, pegboard tasks, and other manual dexterity exercises, delivered in 20 sessions of 60 minutes each, three times per week for about 7 weeks.

Category

Behavior

4

Description

Intervention group 3: sham transcranial direct current stimulation with a two-channel montage, including one channel over the temporoparietal junction and one channel over the left primary motor cortex, plus the integrated phonological and fine motor intervention. Sham stimulation will be applied for only 30 seconds on both channels. The integrated intervention will combine phonological awareness training with targeted fine motor activities linked to reading, such as forming letters with dough and stringing beads marked with phonemes, delivered in 20 sessions of 60 minutes each, three times per week for about 7 weeks.

Category

Behavior

5

Description

Intervention group 4: active transcranial direct current stimulation with the anode over the left temporoparietal junction and the cathode over the right temporoparietal junction, plus phonological awareness training. Active stimulation will be delivered at 1 milliamperes for 20 minutes during the first part of each session, three times per week for 20 sessions over about 7 weeks. Phonological awareness training will be the same as Intervention group 1.

Category

Treatment - Devices

6

Description

Intervention group 5: active transcranial direct current stimulation with the anode over the left primary motor cortex and the cathode over the right supraorbital region, plus non-targeted fine motor training. Active stimulation will be delivered at 1 milliamperes for 20 minutes during the first part of each session, three times per week for 20 sessions over about 7 weeks. Non-targeted fine motor training will be the same as Intervention group 2.

Category

Treatment - Devices

7

Description

Intervention group 6: active dual-site transcranial direct current stimulation with a two-channel montage, including one channel over the temporoparietal junction and one channel over the left primary motor cortex, plus the integrated phonological and fine motor intervention. Each channel will deliver 1 milliamperes for 20 minutes during the first part of each session, three times per week for 20 sessions over about 7 weeks. The integrated intervention will be the same as Intervention group 3.

Category

Treatment - Devices

8

Description

Intervention group 7: active transcranial direct current stimulation with the anode over the left primary motor cortex and the cathode over the right supraorbital region, without any cognitive intervention. Active stimulation will be delivered at 1 milliamperes for 20 minutes per session, three times per week for 20 sessions over about 7 weeks. Participants will watch a silent nature documentary during the session to control for time and attention.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Consultation, Psychological, Research and Specialized Services Center of Isfahan Province General De

Full name of responsible person

Mohammad Amin Javedanfar

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Web page address

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University

Full name of responsible person

Mohammad Amin Javedanfar

Position

PhD Candidate

Latest degree

Master

Other areas of specialty/work

Cognitive Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to confidentiality and ethical considerations related to minor participants, deidentified individual participant data will not be shared.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Study protocol, statistical analysis plan, analytic code, and data dictionary of the randomized, double-blind, sham-controlled trial of simultaneous dual-site transcranial direct current stimulation combined with integrated phonological and fine motor intervention in 9-year-old boys with developmental dyslexia

When the data will become available and for how long

Starting 6 months after publication of the primary results; available for 5 years.

To whom data/document is available

Researchers and academics affiliated with recognized universities and research institutions.

Under which criteria data/document could be used

For scientific and educational purposes only. Requests will be reviewed by the principal investigator for methodological appropriateness and ethical compliance.

From where data/document is obtainable

By email request to the principal investigator: Mohammad Amin Javedanfar, Institute for Cognitive and Brain Sciences, Shahid Beheshti University; m_javedanfar@sbu.ac.ir

What processes are involved for a request to access data/document

Applicants should send a written request by email including their affiliation, purpose of use, and a brief proposal. Requests will be reviewed within 4 weeks; approved documents will be sent electronically.

Comments

There is no further information.