# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

31 Oct 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**

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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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**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 milliampere 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 milliampere 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 milliampere 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 milliampere 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**

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## Sponsors / Funding sources

### 1

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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**
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**Full name of responsible person**
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**Position**
PhD Candidate

**Latest degree**
Master

**Other areas of specialty/work**
Cognitive Psychology

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## Person responsible for updating data

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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.