

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Impact of Phonological Awareness Intervention Combined with Transcranial Direct Current Stimulation on Rapid Automatized Naming and Verbal Short-Term Memory in developmental dyslexia: A Randomized Controlled Trial

Protocol summary

Study aim

This study has two main purposes: First, we are aiming to examine the efficacy of the phonological awareness intervention on rapid automatized naming and verbal short-term memory. Second, we are aiming to explore the efficacy of adjunctive transcranial direct current stimulation to further improve rapid automatized naming and verbal short-term memory.

Design

Sham-control clinical trial, with parallel groups, double-blind, randomized, on 28 patients. The site (www.sealedenvelope.com) was used for randomization.

Settings and conduct

The study will be conducted in the rehabilitation clinic in Tehran individually for each client. Each client will participate in 15 treatment sessions. Both groups will receive phonological awareness therapy, but half will receive active electrical stimulation and the other half will receive sham stimulation. Clients, researcher, evaluator, and data analyst are blinded, and only the assistant therapist will aware of the allocation of groups (double-blinding).

Participants/Inclusion and exclusion criteria

Inclusion criteria were: Persian native language, reading performance at least 1.5 standard deviations below the population mean, a non-verbal IQ score > 85, not having associated disorders or symptoms, absence of a non-compensated hearing loss, and being right-handed. Non-entry criteria included a history of a reading-related intervention, and the use of medication associated with central nervous system disorders.

Intervention groups

1- active stimulation+phonological awareness 2- sham stimulation+phonological awareness

Main outcome variables

rapid automatized naming and verbal short term

memory

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201211049676N2**

Registration date: **2023-02-28, 1401/12/09**

Registration timing: **prospective**

Last update: **2023-02-28, 1401/12/09**

Update count: **0**

Registration date

2023-02-28, 1401/12/09

Registrant information

Name

seyyedeh samaneh mirahadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-04, 1401/12/13

Expected recruitment end date

2023-06-03, 1402/03/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of Phonological Awareness Intervention Combined with Transcranial Direct Current Stimulation on Rapid Automatized Naming and Verbal Short-Term Memory in developmental dyslexia: A Randomized Controlled Trial

Public title

the combined intervention of phonological awareness and transcranial direct current stimulation on Rapid Automatized Naming and Verbal Short Term Memory

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Persian native language reading performance of words and/or non words reading subtests at least 1.5 standard deviations below the population mean according to the NEMA reading and dyslexia test a non-verbal IQ score>85 according to the Wechsler test not having associated disorders or symptoms, including seizures, attention deficit and hyperactivity disorders evaluated by clinical observation and by using Conners' Rating Scales absence of a non-compensated hearing loss and being right-handed as evaluated by the Edinburgh inventory

Exclusion criteria:

a history of a reading-related intervention the use of medication associated with central nervous system disorders

Age

From **7 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

A computer-based randomization approach was used (www.sealedenvelope.com) to randomly assigned participants to the study groups (active/sham). We included 28 participants and 4 blocks of the same size to create a random archive. A unique code generated by the software was given to participants to conceal the randomization process. These unique codes were used on the cubes representing the type of empirical groups; thus, participants will randomly assign to one of these groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

None of the participants, nor the main therapist (researcher) (performing the phonological awareness training in both groups), and the evaluator (evaluating outcome measures at the 5 evaluation time points) will inform of about group allocations. A sealed opaque envelope approach will be used to conceal groupings. The assistant therapist will received the randomly created intervention assignments within the sealed opaque envelopes. After a participant entered the study, the envelope will be unsealed. Just the assistant therapist who set up the tDCS device will be informed of the about intervention allocation (active or sham). Moreover, the investigator who measured outcomes and conducted the analysis will be also blinded to group allocations.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

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Mirdamad avenue

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Approval date

2023-01-24, 1401/11/04

Ethics committee reference number

IR.IUMS.REC.1401.895

Health conditions studied**1****Description of health condition studied**

developmental dyslexia

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

rapid automatized naming and verbal short term memory

Timepoint

baseline, end of the fifth and tenth intervention session, end of the intervention and 6 weeks after intervention

Method of measurement

naming and memory tests

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: active and sham stimulation.

Regardless of group allocation, each participant will go through 15 60-minutes intervention sessions [three times per week (T) for 5 weeks]. Study outcomes will be obtained five times: immediately before treatment (pre-test) (T0), at the end of the fifth intervention session (T1), at the end of the tenth intervention session (T2), immediately after the intervention (T3), and 6 weeks after the end of intervention (T4) by a blinded investigator who will not be involved in other parts of the study. The 6-week follow-up will be planned for each participant to evaluate stability of treatment effects in both groups. "phonological awareness Intervention": phonological awareness treatment will be performed in both, the active and sham groups during each session. Each treatment session will be 60 minutes long (15 hours in total). We will derive the phonological awareness intervention program from the "Gillon Phonological Awareness Training Program". The Gillon PA treatment program covers nine skills: • Rhyme abilities • Phoneme analysis • Phoneme recognition • Phoneme segmentation • Phoneme blending • Tracing speech sounds • Sound-symbol association • Tracing speech sound with letters • Reading and writing skills. "transcranial direct current stimulation intervention (tDCS)": Participants will be randomly assigned to the sham and anodal tDCS groups. In order to determine the location of electrodes accurately, we will use an EEG cap. The anode and cathode electrodes will be positioned over the left and the right parieto-temporal regions, respectively. An Activa Dose II Iontophoresis Delivery Unit tDCS will be used for stimulation. In the active group, stimulation will be performed by two conductive rubber electrodes. Each electrode will be covered by a sponge pad. The 5 cm x 7 cm electrodes will be positioned on the scalp using an elastic rubber strip. Both sides of the sponge pads will be moistened in dextrose 3.33% and sodium chloride 0.3% solution for better conductivity. Before placing the electrodes on the scalp, the therapist will check the skin of the head for lesions. Electrode positions will be identical in both, the anodal and sham tDCS groups. The electrode location over the left and the right hemispheres will be determined as half distance between the T3 and P3, and T4 and P4 electrode positions according to the 10-20 international system. The anodal

electrode will be positioned over the left parieto-temporal cortex, while the cathode will be placed over the right parieto-temporal cortex. In the active tDCS group, at the beginning of stimulation, the current will be gradually increased over the first 30 seconds up to 1 mA, and will be declined gradually to 0 mA over the last 30 seconds of tDCS. A constant direct current of 1 mA will be applied for 20 minutes. In the sham group, the direct current will be applied for 30 seconds and will be turned off afterwards. This placebo intervention induces tDCS-generated sensations (e.g., irritation and itching) indiscernible by the participants from an active intervention. The combined intervention will be applied three times a week for 5 weeks (15 sessions). tDCS will be applied for 15 sessions simultaneously with phonological awareness (During the 60 minutes of the combined intervention, only 20 minutes tDCS (real or sham) will be provided to the participants).

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Iran University of Medical Sciences

Proportion provided by this source

20

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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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

Data is confidential

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available