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 assisstant 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)

Phone

+98 45 3324 6018

Email address

saamaneh.milo@gmail.com

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
Street address
Mirdamad avenue
City
Tehran
Province
Tehran
Postal code
158754391
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 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. Electrodes 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
Department of Education of Tehran Province

Full name of responsible person
Alireza karimian

Street address
felestin avenue

City
Tehran

Province
Tehran

Postal code
1416633455

Phone
+98 21 8896 1126

Email
info@medu.gov.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
دکتر سمیده خوپی

Street address
hemmat anenue

City
تهران

Province
Tehran

Postal code
1449614535

Phone
+98 21 86701

Email
Schoolofmedicine@iums.ac.ir
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
Iran University of Medical Sciences
Full name of responsible person
dr reyhane mohamadi
Position
Associate proffesor
Latest degree
Ph.D.
Other areas of specialty/work
Speech therapy
Street address
mirdamad avenue
City
تهران
Province
Tehran
Postal code
1545913487
Phone
22227124
Email
mohamadi.r@iums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
dr seyyedeh samaneh mirahadi
Position
speech therapist
Latest degree
Ph.D.
Other areas of specialty/work
Speech therapy
Street address
29 bahman avenue
City
Tabriz
Province
East Azarbaijan
Postal code
5164736931
Phone
+98 41 3337 2072
Email
saamaneh.milo@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
dr seyyedeh samaneh mirahadi
Position
speech therapist
Latest degree
Ph.D.
Other areas of specialty/work
Speech therapy
Street address
29 bahman avenue
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Phone
+98 41 3335 5921
Email
saamaneh.milo@gmail.com

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