

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 2026

Comparison of the effect of Phonological Awareness (PA), grapheme to phoneme knowledge treatments, and transcranial direct current stimulation (TDCS) on PA and reading skills in reading disabled students.

Protocol summary

Study aim

The use of combination therapy (instrumental and behavioral) and comparison of treatment results with behavioral therapy on phonological awareness (PA) skills (Phoneme: The sounds of a language that the words are created by putting the phonemes together. PA: The ability to consciously identify and manipulate phonemes and change their position in the word and thus change the word to another one. Example: The phoneme "s" is changed in the word "sir" and the phoneme "sh" is replaced and the word "sir" is changed to "shir") and word and non-word reading

Design

A concealed, randomized, blinded, sham-active clinical trial with a parallel-group design of 28 patients, enrolled between December 2020 and June 2021 and followed for one month

Settings and conduct

Intervention in this study in a private clinic in Tehran by a therapist for 15 sessions. Both participants and therapist are blind to whether the participant is in the control or intervention group

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Having a mental age commensurate with the second to fifth grades - Non-verbal intelligence benefit above 80 - Having phonological dyslexia - Being monolingual (Persian) Criteria for not entering: - Having a history of speech therapy in the field of language therapy, especially phonological awareness, Having comorbidities or disorders including: hearing loss, epilepsy, IQ, attention deficit / hyperactivity disorder - Taking drugs related to diseases of the nervous system - The presence of a metal object (shunt, etc.) in the head and neck - The presence of a battery in the heart

Intervention groups

Treatment group: providing Phonological awareness (PA) and Transcranial direct current stimulation Control

group: Providing PA and Sham Stimulation

Main outcome variables

Word, nonword reading and Phonological Awareness

General information

Reason for update

Acronym

TDCS, PA

IRCT registration information

IRCT registration number: **IRCT20201211049676N1**

Registration date: **2021-04-20, 1400/01/31**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-20, 1400/01/31**

Update count: **0**

Registration date

2021-04-20, 1400/01/31

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

2020-12-30, 1399/10/10

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of Phonological Awareness (PA), grapheme to phoneme knowledge treatments, and transcranial direct current stimulation (TDCS) on PA and reading skills in reading disabled students.

Public title
Effects of transcranial direct current stimulation and Phonological Awareness treatment in Dyslexia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
mental age commensurate with second to fifth grades
Non-verbal IQ higher than 80 having phonological dyslexia Right handedness Monolingualism (Persian)
Exclusion criteria:

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **28**
More than 1 sample in each individual
Number of samples in each individual: **1**
Each participants provides one sample

Randomization (investigator's opinion)
Randomized

Randomization description
In order to allocate randomly, the random blocks method with blocks 4 size will be used. According to the sample size of 32 that has been determined, 8 quadruple blocks will be produced using the online site (www.sealedenvelope.com). In order to apply concealment in the randomization process, unique codes will be used on the boxes that determine the type of intervention, and the mentioned code is also generated by the software.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study undermentioned persons will be blind: - Evaluator relative to pre and post-intervention assessments - Therapist relative to Sham-active intervention execution (Sham: The placebo state in which the device electrodes are placed on the scalp to create a placebo effect, but no current is sent to the brain. Active: Anodal stimulation mode (positively

charged) where the electrodes are on the scalp and a current of 1mili Amper (mA) is directed to the brain for 20 minutes. - Participants relative to receiving Sham-active intervention execution

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
No.14, 18 metri Ave,
City
Ardabil
Province
Ardabil
Postal code
5619656435

Approval date
2021-03-08, 1399/12/18

Ethics committee reference number
IR.IUMS.REC.1399.1377

Health conditions studied

1

Description of health condition studied
Dyslexia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
word reading (high frequency, average frequency, low frequency)

Timepoint
Baseline, end of the fifth treatment session, end of the tenth treatment session, end of the final treatment session, one month later (follow up)

Method of measurement
Reading test

2

Description
Phonological awareness

Timepoint

Baseline, end of the fifth treatment session, end of the tenth treatment session, end of the final treatment session, one month later (follow up)

Method of measurement

Phonological awareness test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Treatment - Devices

2

Description

Control group:

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

مدارس ابتدایی

Full name of responsible person

Reyhane mohamadi

Street address

Mirdamad Ave, Shahnazri Ave, Nezam Alley, Tehran, Iran

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Province

Tehran

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15459-13487

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

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

10

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

Reyhane mohamadi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Speech therapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyyedeh samaneh mirahadi

Position

Ph.D student

Latest degree

Master

Other areas of specialty/work

Speech therapy

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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

The participant data file is confidential and only general information will be entered in the article.

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

Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Seyyede samaneh mirahadi

Position

Ph.D student

Latest degree

Master

Other areas of specialty/work

Speech therapy