

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Sep 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

##### City

Tehran

##### Province

Tehran

##### Postal code

15459-13487

##### Phone

+98 21 2222 8052

##### Email

rehab@iums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Reyhane mohamadi

##### Street address

Mirdamad Ave, Shahnazri Ave, Nezam Alley

##### City

Tehran

##### Province

Tehran

##### Postal code

15459-13487

##### Phone

+98 21 2222 8052

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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

##### Street address

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mohamadi.r@iums.ac.ir

## 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