

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Investigation into efficacy of an auditory training program based on interaural interaction in children with specific learning disorder

Protocol summary

Study aim

Investigation into efficacy of an auditory training program based on interaural interaction in children with specific learning disorder

Design

Clinical trial with control group, Participants are selected non-randomly for each group

Settings and conduct

The intervention part of this study includes an auditory training program (designing, building and implementation are doing in this study). The participants are learning disorder children (7 to 12 years old), in the Isfahan city learning disorder centers and in two intervention and control groups. The intervention group will use the auditory training program for 3 months.

Participants/Inclusion and exclusion criteria

Age range between 7-12 years old, Normal auditory thresholds (<20dB HL) within 250 to 8000Hz frequency range, Definite diagnosis of specific learning disorder by psychologist based on DSM-5 Criteria, Teacher or parents report about some problem in sound localization and speech perception in noise- Abnormal MLD Test result (MLD < 7dB) Abnormal PARWIN test result. /Music training or participating in the other rehabilitative programs, History of ear disease

Intervention groups

Intervention includes an auditory training program designed based on binaural Processing in brainstem level. People will be divided in two intervention and control groups non-randomly.

Main outcome variables

MLD and Persian auditory recognition of words-in-noise (PARWIN) are the main variables of this survey.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210522051359N1**

Registration date: **2021-07-04, 1400/04/13**

Registration timing: **prospective**

Last update: **2021-07-04, 1400/04/13**

Update count: **0**

Registration date

2021-07-04, 1400/04/13

Registrant information

Name

Marziyeh Moallemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2225 0541

Email address

marziyehmoallemi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-12-11, 1400/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation into efficacy of an auditory training program based on interaural interaction in children with specific learning disorder

Public title

Effect of central auditory training on learning disorder

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

-Age range between 7-12 years old , Normal auditory thresholds (<20dB HL) within 250 to 8000Hz frequency range Hearing in both ears symmetrically (difference thresholds <10 dB) Definite diagnosis of specific learning disorder by psychologist based on DSM-5 Criteria (normal vision, minimum cognitive and intelligence skills are among this criteria) Right-handedness (using Edinburgh handedness inventory) Word recognition score in quiet $\geq$ 90% Being monolingual (Farsi as a native language) Teacher or parents report about some problem in sound localization and speech perception in noise- Abnormal MLD Test result (MLD < 7dB) Abnormal PARWIN test result

Exclusion criteria:

Music training Participating in the other rehabilitative programs History of neurological and psychological disorders History of any ear disease Taking medication

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

There is an intervention and two groups...one group receive rehabilitation and the other group (control group) don't receive any intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University Campus, Hemmat freeway, next to Milad tower, Tehran,

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2020-06-16, 1399/03/27

Ethics committee reference number

IR.IUMS.REC.1399.300

Health conditions studied

1

Description of health condition studied

Learning disorder

ICD-10 code

F81.9

ICD-10 code description

Developmental disorder of scholastic skills, unspecified

Primary outcomes

1

Description

Masking level difference (MLD) and Persian auditory recognition of words-in-noise

Timepoint

Before, immediately after intervention, and 45 days after the completion of intervention

Method of measurement

MLD test and Persian auditory recognition of words-in-noise (PARWIN) test

Secondary outcomes

1

Description

Recognition of Persian randomized dichotic digits and Auditory communication improvement

Timepoint

Before, immediately after completing intervention, and 45 days after the completion of intervention

Method of measurement

PRDDT test and questionnaire

Intervention groups

1

Description

Intervention group are children with learning disorder in 7 -12 years old range who are candidates for receiving an auditory training program based on binaural interaction. They will use the designed rehabilitation program for 3 months (36 sessions), and will be assessed by behavioural tests before and after the intervention. The mentioned program is designated based on auditory

brainstem function and is usable as an Application. Five important auditory function are included in the program.

Category

Rehabilitation

2

Description

Control group: Children with Learning disorder in 7 -12 years old range with no intervention.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan centers for Learning disorder

Full name of responsible person

Marziyeh Moallemi

Street address

No 15, Artesh Ave

City

Isfahan

Province

Isfahan

Postal code

1545913487

Phone

+98 21 2225 0541

Email

marziyehmoallemi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyyed Abbas Motevallian

Street address

near Milad Tower, Shahid Hemmat Highway. Tehran

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Phone

+98 21 8670 2503

Email

research-m@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

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

Iran University of Medical Sciences

Full name of responsible person

Marziyeh Moallemi

Position

Ph.D candidate

Latest degree

Master

Other areas of specialty/work

Audiology

Street address

Audiology Department, Faculty of Rehabilitative, Shah Nazari Ave, Mirdamad Blvd

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2222 8951

Email

marziyehmoallemi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Marziyeh Moallemi

Position

ph.D Candidate

Latest degree

Master

Other areas of specialty/work

Audiology

Street address

Audiology Department, Faculty of Rehabilitative, Shah Nazari Ave, Mirdamad Blvd

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2222 8951

Email

marziyehmoallemi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Marziyeh Moallemi

Position

Ph.D Candidate

Latest degree

Master

Other areas of specialty/work

Audiology

Street address

Audiology Department, Faculty of Rehabilitative, Shah
Nazari Ave, Mirdamad Blvd

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2222 8951

Email

marziyehmoallemi@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available