

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of rehabilitation training based on temporal fine structure on speech in noise perception performance on elderly with mild to moderate hearing loss

Protocol summary

Study aim

Effect of TFS based rehabilitation training on the binaural temporal fine structure processing and speech performance in noise in elderly with mild to moderate hearing loss

Design

Clinical trial with a control group, single blind, randomized

Settings and conduct

The study population is aged 60-75 years old with mild to moderate hearing loss referring to the Audiology Clinic of the Faculty of Rehabilitation Sciences of Iran University of Medical Sciences. The statistical sample will be selected based on the inclusion criteria for entering the present study and will be divided into two groups of study and control group (which will not receive rehabilitation).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 60 to 75 years, Mild to moderate hearing loss, Lack of central nervous system diseases and lack of history of head trauma, epilepsy, No use of nerves drugs, Disturbance in Speech Noise Tests, Binaural TFS, Being Right handed, Acquisition lack of cognitive disorders based on the evaluation results of the MMSE cognitive status examination, Being monolingual, Lack of professional music experience, Ability to collaborate on tests. Exclusion criteria: □ Unwillingness to collaborate and participate in the research project at each stage, □ Inability of the individual to perform any of the tests for reasons such as insufficient focus.

Intervention groups

Intervention of rehabilitation training in the elderly with mild to moderate hearing loss

Main outcome variables

Speech in noise score in elderly people with mild to moderate hearing loss will increase.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190625044006N1**

Registration date: **2019-08-07, 1398/05/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-07, 1398/05/16**

Update count: **0**

Registration date

2019-08-07, 1398/05/16

Registrant information

Name

Parisa Rasouli fard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2227 0117

Email address

rasoulifard.p@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-12, 1398/04/21

Expected recruitment end date

2019-09-20, 1398/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of rehabilitation training based on temporal fine structure on speech in noise perception performance on elderly with mild to moderate hearing loss

Public title

The effect of rehabilitation training on speech performance on elderly

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 60 to 75 years Mild to moderate hearing loss: Adaptation of the air conduction over the bone conduction, this means that the air conduction and bone conduction of the thresholds are up to 2000 Hz below 25 dB and from frequency of 2000 to 8000 Hz between 25 and 70 dB Normal state of the middle ear (Type A tympanometry) Lack of central nervous system diseases and lack of history of head trauma, epilepsy No use of nerves drugs Disturbance in speech recognition tests in noise, Binaural TFS Right handed Acquisition of lack of cognitive impairment based on the evaluation results of the MMSE cognitive status examination Being monolingual No professional music experience Ability to collaborate on tests

Exclusion criteria:

Age

From **60 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **12**

More than 1 sample in each individual

Number of samples in each individual: **0**

Select eligible people according to inclusion criteria

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants were kept blind in this study.

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Science

Street address

Thirteenth floor. block A. Central Head quarters of the Ministry of Health and Medical Education. simaye Iran st. between South Falamak and Zarafshan. Ghods Town (West)

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-02-23, 1397/12/04

Ethics committee reference number

IR.IUMS.REC.1398.003

Health conditions studied

1

Description of health condition studied

presbycusis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Speech in noise score

Timepoint

Before starting the study and 5 weeks later

Method of measurement

Parwin speech in noise test

Secondary outcomes

1

Description

Interaural phase difference perception

Timepoint

Before starting the study and 5 weeks later

Method of measurement

TFS_LF test

Intervention groups

1

Description

Intervention group: Elderly with mild to moderate hearing loss. Intervention type: Rehabilitation program. Program schedule: 5 weeks (3 times a week). Designed by Engineering Software and Medical Engineering Group

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of rehabilitation, Iran university of medical sciences

Full name of responsible person

Parisa Rasouli fard

Street address

Faculty of rehabilitation science, Madadkaran St, Shahnazari St, Mirdamad Blvd

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2225 0541

Email

parisa_rasouli38@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr kazem Malakooti

Street address

Iran University of Medical Sciences, West Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2503

Email

research@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

Parisa Rasouli fard

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Audiology

Street address

Madadkaran ave.,Mirdamad Blvd.

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2227 0117

Fax

Email

rasoulifard.p@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Parisa Rasouli fard

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Audiology

Street address

Madadkaran ave.,Mirdamad Blvd.

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2227 0117

Fax

Email

rasoulifard.p@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Parisa Rasouli fard

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Audiology

Street address

Madadkaran ave., Mirdamad Blvd.

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2227 0117

Fax**Email**

rasoulifard.p@iums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

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

Data Dictionary

Not applicable

Title and more details about the data/document

The results are after rehabilitation.

When the data will become available and for how long

Get started 1 year after publishing articles and results.

To whom data/document is available

Accessibility is available to everyone.

Under which criteria data/document could be used

There are no special conditions.

From where data/document is obtainable

Responsible person: Parisa Rasouli fard

parisa_rasouli38@yahoo.com 00982122270117

What processes are involved for a request to access data/document

After receiving the email from the person concerned and reviewing his proposal, the documents will be delivered to him one month later.

Comments