Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Oct 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)

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+98 21 2227 0117

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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

Rehabilitation

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

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

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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

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1449614535

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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
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

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Person responsible for updating data

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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