

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 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

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

**Street address**

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

**City**

Tehran

**Province**

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**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

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**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

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## 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**

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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**