

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### The Effect of Auditory Training program Designed Based on Temporal Processing on the Auditory Skills of Elderly Hearing Aid Users

#### Protocol summary

##### Study aim

The Effect of Auditory Training program Designed Based on Temporal Processing on the Auditory Skills of Elderly Hearing Aid Users

##### Design

Randomized clinical trial with control group

##### Settings and conduct

This study will be conducted in two parts. part 1: based on the theoretical framework of temporal processing, auditory training program will be designed as a software, part 2: the effect of the auditory training program on 60-75 years old elderly hearing aid users referred to the audiology clinic of the Faculty of Rehabilitation of Iran University of Medical Sciences will be evaluated in two groups of control and intervention. The intervention group will use the auditory training program for 3 months (36 sessions) and then the results of the central and electrophysiological tests in both groups will be compared before, immediately after the intervention, and one month thereafter.

##### Participants/Inclusion and exclusion criteria

An elderly population, 60-75 years old, Bilateral mild to moderate Sensory Neural Hearing Loss symmetrically, Auditory thresholds 40 dB < and > 55 dB within the 500-4000 Hz frequency range, candidates for binaural hearing aids, normal condition of middle ear function, ensuring lack of salient cognitive problems using Mini Mental State Examination MMSE), right-handedness ; speaking Farsi and being monolingual

##### Intervention groups

Intervention includes an Auditory Training program Designed Based on Temporal Processing. People will be divided in two intervention and control groups. People in control group will not receive any rehabilitation interventions.

##### Main outcome variables

Quick-SIN and GIN score in elderly hearing aid users are the main variables of this survey.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190921044838N1**

Registration date: **2019-12-25, 1398/10/04**

Registration timing: **prospective**

Last update: **2019-12-25, 1398/10/04**

Update count: **0**

##### Registration date

2019-12-25, 1398/10/04

##### Registrant information

##### Name

Karim Sattari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2288 5910

##### Email address

ka\_sattari@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-21, 1398/11/01

##### Expected recruitment end date

2020-03-19, 1398/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Auditory Training program Designed Based on Temporal Processing on the Auditory Skills of Elderly Hearing Aid Users

**Public title**

The Effect of Rehabilitation Program on the Auditory Skills of Elderly Hearing Aid Users

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

An elderly population, 60-75 years old Bilateral mild to moderate Sensory Neural Hearing Loss Auditory thresholds 40 dB < and > 55 dB within the 500-4000 Hz frequency range Hearing in both ears symmetrically (mean difference thresholds about 5 dB) Candidates for binaural hearing aids Normal condition of middle ear function Ensuring lack of salient cognitive problems using Mini Mental State Examination MMSE) Right-handedness (using Edinburg handedness inventory) Speaking Farsi and being monolingual

**Exclusion criteria:****Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **16**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Factorial

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Iran National committee for Ethics in Biomedical Research

**Street address**

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between South Falamak & Zarafshan, Ghods Town

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2018-12-09, 1397/09/18

**Ethics committee reference number**

IR.IUMS.REC.1397.652

**Health conditions studied****1****Description of health condition studied**

Central Auditory Processing Disorder and Speech in Noise Perception Problem

**ICD-10 code**

H90.5

**ICD-10 code description**

Unspecified sensorineural hearing loss

**Primary outcomes****1****Description**

Signal to Noise Ratio Loss index (SNR Loss)

**Timepoint**

Before, immediately after completing intervention, and one month after the completion of intervention

**Method of measurement**

QuickSIN Test

**2****Description**

Score of the Gap In Noise (GIN) Test

**Timepoint**

Before, immediately after completing intervention, and one month after the completion of intervention

**Method of measurement**

Gap In Noise (GIN) Test

**3****Description**

Score of the Duration Pattern Test (DPT)

**Timepoint**

Before, immediately after completing intervention, and one month after the completion of intervention

**Method of measurement**

Duration Pattern Test (DPT)

**4****Description**

Speech ABR Waves Latencies

**Timepoint**

Before, immediately after completing intervention, and one month after the completion of intervention

**Method of measurement**

Speech ABR Test

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### **Description**

Speech ABR Waves amplitude

### **Timepoint**

Before, immediately after completing intervention, and one month after the completion of intervention

### **Method of measurement**

Speech ABR Test

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Hearing-impaired elderly 60-75 years old who are candidates for binaural hearing aid will use a designed rehabilitation program for 3 months (36 sessions), and the results of central and electrophysiological tests will be compared before, immediately after the intervention, and one month after the intervention.

#### **Category**

Rehabilitation

### 2

#### **Description**

Control group: No Intervention

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Audiology Clinic of Faculty of rehabilitation, Iran university of medical sciences

##### **Full name of responsible person**

Karim Sattari

##### **Street address**

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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1545913487

##### **Phone**

+98 21 2225 0541

##### **Email**

ka\_sattari@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**

1545913487

##### **Phone**

+98 21 8670 2503

##### **Email**

research@iums.ac.ir

##### **Web page address**

http://vcr.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**

Karim Sattari

##### **Position**

PhD 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**

ka\_sattari@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Karim Sattari

**Position**

PhD candidate

**Latest degree**

Master

**Other areas of specialty/work**

Audiology

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**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

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PhD candidate

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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**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Reporting as a PhD dissertation and papers

**When the data will become available and for how long**

2020 and after

**To whom data/document is available**

All

**Under which criteria data/document could be used**

In accordance with Iran University of Medical Sciences copyright

**From where data/document is obtainable**

Databases for papers, Library of the School of Rehabilitation, IUMS, for dissertation

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

For papers depends on the journal's policy For the dissertation, studying in the library

**Comments**