Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Oct 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

5

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
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1545913487
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+98 21 2225 0541
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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
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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
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