Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of Auditory Localization Training on Speed Processing and Speech Perception in Elderly with Difficulty in Speech Perception-In-Noise

Protocol summary

Study aim
Effects of auditory localization training on speed processing and speech perception in elderly with difficulty in speech perception-in-noise

Design
A control clinical trial with a parallel groups, randomized using blocking on 36 elderly

Settings and conduct
After visiting Rofideh Hospital Elderly Clinic and the components of the initial hearing assessment, the P-SSQ questionnaire will be completed and the localization and Q-SIN tests will be performed. Persian version of MMSE test, speech compression test with time compression, consonant-vowel test in the presence of noise, word recognition in the presence of noise, reaction time test, electrophysiology test ALLR, then divided into two groups and for 10 to 12 sessions undergo hearing localization rehabilitation at the end of the rehabilitation period and one month after that the assessments are repeated.

Participants/Inclusion and exclusion criteria
Age range 65-75 years;Hearing range better than 25 dBHL at frequencies of 250 to 4000 Hz and symmetrical hearing in both ears ;Complaints of difficulty understanding speech in crowded environments:Score Low (less than 7) in the Persian version of the P-SSQ questionnaire; signal to noise ratio index above 7dB in the Persian version of the Q-SIN test; the normal middle ear status and the normal results of acoustic reflex and tympanometry, tympanogram Type A and static compliance from 0.3 to 1/6;Having a minimum score of 25 in the MMSE assessment; No neurological and autological disorders; No history of neurological and mental diseases ; Persian language

Intervention groups
Group A (Intervention): Elderly receiving localization rehabilitation - Group B (Control): Elderly receiving no localization rehabilitation

Main outcome variables
Improving the ability to understand speech in noise in the elderly using localization based rehabilitation; Improve speech processing speed impairment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210220050431N1**
Registration date: **2021-03-21, 1400/01/01**
Registration timing: **prospective**

Last update: **2021-03-21, 1400/01/01**
Update count: **0**

Registration date
2021-03-21, 1400/01/01

Registrant information

Name
Jafar Aghazadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-21, 1400/02/01

Expected recruitment end date
2022-03-06, 1400/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of Auditory Localization Training on Speed Processing and Speech Perception in Elderly with Difficulty in Speech Perception-In-Noise

Public title
Auditory Localization training

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Hearing range better than 25 dBHL at frequencies from 250 to 4000 Hz and symmetrical hearing in both Ears (mean threshold difference about 5 dB) Complaining and expressing difficulty in understanding speech in crowded environments Low score (less than 7) in The Persian version of The .P-SSQ questionnaire Signal to noise ratio Index (SNRLOSS) above 7 dB in the Persian version of the Q-SIN test Normal status of the middle ear and normal results of the acoustic reflex and tympanometry, tympanogram type A and static compliance from 0.3 to 1.6 Earn a minimum of 25 Points in the MMSE evaluation No neurological and autologic disorders Lack of a history of neurological and mental disorders Persian language Age range 65 to 75 years

Exclusion criteria:
Reluctance to collaborate at any stage of research Loss of any of the changeable input criteria

Age
From **65 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, block randomization method was used for random allocation. Using the website "sealed envelope.com", the statistician designed this two-group experiment of 6 blocks (including 3 participants in the intervention group and 3 participants in the control group). Blocking is usually done to balance The number of samples assigned to each of the study groups should be used. This feature helps researchers to equate the number of samples assigned to each of the study groups in cases where intermediate analyzes are required during the sampling process. The size of all the blocks is the same and we will have. Randomization tool also uses random allocation software (software allocation Random) that these random sequence generation software in addition to simple randomization are able to generate random sequence by blocking method. For concealment we use concealment allocation. The sample allocation ratio will be (1: 1 Allocation). Then, based on the obtained blocks, the sequence of allocation of rehabilitation exercises will be given to the patients.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of University of Social Welfare and Rehabilitation Sciences

Street address
Kodakyar Ave, Daneshjo Blvd, Evin (Velenjak)

City
Tehran

Province
Tehran

Postal code
1985713871

Approval date
2020-01-14, 1398/10/24

Ethics committee reference number
IR.USWR.REC.1398.162

Health conditions studied

1

Description of health condition studied
Speech Perception difficulty in noise

ICD-10 code
H93.2

ICD-10 code description
Other abnormal auditory perceptions

Primary outcomes

1

Description
Time compressed speech test score

Timepoint
Before starting rehabilitation, immediately after the end of rehabilitation, one month after the end of rehabilitation

Method of measurement
Percentage of repetition of words heard

2

Description
Word recognition score in noise
Timepoint
Before starting rehabilitation, immediately after the end of rehabilitation, one month after the end of rehabilitation
Method of measurement
Correct recognition of word

3

Description
Consonant-Vowel in Noise Test Score
Timepoint
Before starting rehabilitation, immediately after the end of rehabilitation, one month after the end of rehabilitation
Method of measurement
Percentage of Correct recognition of syllables

4

Description
Reaction time
Timepoint
Before starting rehabilitation, immediately after the end of rehabilitation, one month after the end of rehabilitation
Method of measurement
Using the software in milliseconds

5

Description
latency of N1-P2 wave
Timepoint
Before starting rehabilitation, immediately after the end of rehabilitation, one month after the end of rehabilitation
Method of measurement
Using the software in milliseconds

6

Description
Amplitude of N1-P2 wave
Timepoint
Before starting rehabilitation, immediately after the end of rehabilitation, one month after the end of rehabilitation
Method of measurement
Using the software in microvolts

7

Description
Interaural Time Difference
Timepoint
Before starting rehabilitation, immediately after the end of rehabilitation, one month after the end of rehabilitation
Method of measurement
Indicate the location of the audio source

Secondary outcomes

empty

Intervention groups

1

Description
Localization training sessions are held twice a week, for 45 minutes each time for 10 to 12 sessions per person. Two high- pass noise and low-pass noise stimuli with a cut-off point of 2 kHz, a delay of 250 milliseconds and a fall time of 20 milliseconds will be used.Sounds with different ITDs are provided through headphones, and the person must respond by indicating where the sound source is perceived. Stimulus will be offered binaurally with time differences of 880, 660, 440, 220, 0, -220, -440, -880 microseconds in the intensity of 50 dBHL. Negative and positive represent the left and right ears.Each ITD is rehearsed with the person several times to be well recognizable to the individual and the individual must indicate the location of the audio source.
Category
Rehabilitation

2

Description
Control group: No rehabilitation will be performed for the control group, but after the completion of the project, it is suggested that if desired, the same rehabilitation period be performed for them.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Rofiedeh Rehabilitation Hospital
Full name of responsible person
Dr.Saeideh Merhkian
Street address
Nemati Aly. South Salimi Ave. Andarzgou Blv.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Dr. Hamidreza Khorramkhorshid
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Kodakyar Ave.Daneshjo. Blv.Evin
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19585713871
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Email
rd@uswr.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences
Full name of responsible person
Jafar Aghazadeh
Position
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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

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

All potential data can be shared after de-identifying individuals.

When the data will become available and for how long

Access period starts 3 months after the results are published.

To whom data/document is available

The data of this study will be avalable to researchers working in academic and scientific institution.

Under which criteria data/document could be used

Futur analysis of the delivered date will be possible only with the coordination of the main researcher.

From where data/document is obtainable

Applicant can submit their application by sending an email to the lead researcher.

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

The request is first submitted to the principal investigator. The data is then send to the applicant in coordination with other research colleagues and in determining the applicants purpose.

Comments