Clinical Trial Protocol  
Iranian Registry of Clinical Trials  
26 Aug 2019

The effects of “auditory spatial training” on informational masking release with Persian version of coordinate response measure (CRM) in elderly normal hearing listeners

Protocol summary

Study aim
The effects of spatial hearing training on informational masking release with Persian version of CRM in normal hearing elderly listeners

Design
A Clinical trial with a control and an intervention group design of 15 patients in each group, enrolled between February and August 2019.

Settings and conduct
To evaluate the effects of spatial hearing training, all participated will be evaluated in three phases: before spatial hearing training, during and after that at Iran University of Medical Sciences Audiology clinic. We will use the speech in noise tests and self assessment questionnaire to evaluate the training effects.

Participants/Inclusion and exclusion criteria
To evaluate the effects of spatial hearing training on informational masking release the elderly people with speech in noise perception difficulties will participate. All of the participants must have no cognition problems. For better cooperation in rehabilitation sessions only 60 to 75 year old elderly will participate.

Intervention groups
According to 5 important signs of informational masking release, the spatial hearing training is designed. These cues are: spatial separation between target and masker signals, speech in noise ratio, similarity and difference between target and masker signals, the same or different sex of target and masker signals and meaningful or non-meaningful of maskers. People will be divided in two intervention and control groups. People in control group will not receive any rehabilitation interventions.

Main outcome variables
The amount of informational masking is the main variable and SSQ score is the secondary outcome of this survey.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT20190118042404N1

Registration date: 2019-02-25, 1397/12/06  
Registration timing: registered_while_recruiting

Last update: 2019-02-25, 1397/12/06  
Update count: 0

Registration date
2019-02-25, 1397/12/06

Registrant information
Name
Marzieh Amiri  
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-19, 1397/11/30  
Expected recruitment end date
2019-07-22, 1398/04/31

Actual recruitment start date
empty  
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of “auditory spatial training” on informational masking release with Persian version of coordinate response measure (CRM) in elderly normal hearing listeners

Public title
The effects of spatial auditory training on speech in noise perception in elderly

Purpose
Supportive
Inclusion/Exclusion criteria

Inclusion criteria:
All of 60 to 75 year old people who are suffering from speech in noise perception

Exclusion criteria:
Normal hearing thresholds in 250 to 4000 Hz No cognition impairment according to Mini mental state examination(MMSE). High school diploma degree and upper The age between 60 to 75 years old Right handedness Be Persian Speech perception in noise difficulty Normal middle ear function

Age
From 60 years old to 75 years old

Gender
Both

Phase
N/A

Groups that have been masked
None

Sample size
Target sample size: 30

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

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 Sciences

Street address
Iran University of Medical Sciences, Near Milad Tower, Hemmat Highway

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2018-08-26, 1397/06/04

Ethics committee reference number
IR.IUMS.REC.1397.303

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
Informational masking

Timepoint
Sentence correct recognition score with Persian version of Coordinate Response Measure(CRM) in three times: before the training, immediately and 1 month after that

Method of measurement
Informational masking test

Secondary outcomes

1

Description
Speech, Spatial and Qualities of Hearing Scale(SSQ) score

Timepoint
In three times: before the training and immediately and 1 month after that

Method of measurement
Measure a listener's self-reported ability to hear in a variety of everyday situations according to SSQ sub tests: speech perception, spatial hearing and quality of hearing according to a 10 degree scale

Intervention groups

1

Description
Intervention group: The people with even numbers will participate in this group. Rehabilitation sessions will be divided into some main categories: sessions with nonmeaningful competing signals such as white noise and sessions with meaningful distractive signals such as babble noise and some sentences. In all of the spatial training sessions the target signal will present from the 0 azimuth degree and the competing maskers will present from + and - 90 azimuth degree. We will use the Persian version of Quick SIN as a target signals. Every session will start from the signal to noise ratio which patient will respond correctly to less than 50 percent of sentences and will continue until 30 minutes. Training sessions will continue for 6 weeks and every week patient will participated in two sessions.
Category
Rehabilitation

2
Description
Control group: The persons with odd numbers will be in the control group. These people must not receive any rehabilitative programs during this study. All of the participated persons of our study are suffering from speech in noise perception, so we will guarantee that if our designed spatial training has a significant value on the speech in noise perception we will administrate that to all of the control group persons.

Category
Rehabilitation

Recruitment centers

1
Recruitment center
Name of recruitment center
Audiology clinic of Faculty of Rehabilitative of Iran University of Medical Sciences
Full name of responsible person
Marzieh Amiri
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Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seyyed Kazem Malakouti
Street address
Vice chancellor for research, Vice chancellor for International Affairs, Iran University of Medical Sciences, near Milad Tower, Shahid Hemmat Highway. Tehran
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Tehran
Postal code
139913450
Phone

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
Marzieh Amiri
Position
PhD student of audiology
Latest degree
Master
Other areas of specialty/work
Audiometry
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Person responsible for scientific inquiries
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Iran University of Medical Sciences
Full name of responsible person
Farnoush Jaroolahi
Position
Associate professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available