

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of audio-visual integration and recalibration of auditory space in unilateral hearing loss pre and post auditory localization training using ventriloquism effect

#### Protocol summary

##### Study aim

Evaluation of the effects of Localization training on the of adaptation and recalibration of auditory spatial perception and its effects on the Ventriloquism Effect (VE) and the Ventriloquism After Effect VAE

##### Design

Clinical trial with a control group, the study will be performed on 50 subjects

##### Settings and conduct

Samples are selected from people referring to the audiology department of the Faculty of Rehabilitation Sciences. After grouping Based up on Inclusion criteria, initial evaluations are performed. Then the intervention is applied and then the tests are repeated.

##### Participants/Inclusion and exclusion criteria

Normal Group: Normal Hearing and Vision People Lack of skill in music and being right hand Experiment group: People with Unilateral Chronic Hearing loss Lack of skill in music and being right hand and Normal Vision

##### Intervention groups

1- Experimental group are patients with chronic unilateral conductive hearing loss who receive localization training intervention. This intervention will improve the reduced auditory localization ability in this group and will ultimately improve the audio-visual integration. 2- The normal group also receives the intervention. To show the effect of the intervention in the experimental group, the normal group also receives the intervention. This intervention will improve the auditory localization performance and reduce its error. The end result will be an increase in audio-visual integration capabilities in this group

##### Main outcome variables

Basic localization Ability Ventriloquism Effect Ventriloquism After Effect

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220206053952N1**

Registration date: **2022-04-11, 1401/01/22**

Registration timing: **prospective**

Last update: **2022-04-11, 1401/01/22**

Update count: **0**

##### Registration date

2022-04-11, 1401/01/22

##### Registrant information

##### Name

Farnoush Jarollahi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2225 0541

##### Email address

jarollahi.f@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-05-11, 1401/02/21

##### Expected recruitment end date

2022-10-23, 1401/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation of audio-visual integration and recalibration of auditory space in unilateral hearing loss pre and post auditory localization training using ventriloquism effect

## Public title

Evaluation of audio-visual integration in unilateral hearing loss

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Inclusion criteria in the norm group: Normal hearing thresholds (based on goodman 1965) Normal middle ear function Absence of external ear anomalies No history of ear surgery Not taking drugs that affect the CNS such as antiepileptic drugs and ... Norm vision Being right-handed No history of professional activity in music unilateral chronic hearing loss group: Presence of conductive hearing loss in the right ear, with more than 30 dB HL Hearing loss has lasted for at least 6 months Absence of external ear anomalies Absence of cerumen and foreign body in the ear canal No history of ear surgery Not taking drugs that affect the CNS such as antiepileptic drugs and ... Normal vision Being right-handed No history of professional activity in music

### Exclusion criteria:

Reluctance to continue participating in the study at any stage

## Age

From **18 years** old to **40 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Other

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committees of Iran University of

Medical Sciences

#### Street address

Audiology department, School of Rehabilitation Sciences, Iran University of Medical Sciences Maddadkaran St., Shahid Nazari St., Mother Square, Mirdamad Blvd, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran

#### City

TEHRAN

#### Province

Tehran

#### Postal code

15459-13487

#### Approval date

2022-02-19, 1400/11/30

#### Ethics committee reference number

IR.IUMS.REC.1400.1077

## Health conditions studied

### 1

#### Description of health condition studied

Poor Auditory Localization( Central )

#### ICD-10 code

H93.25

#### ICD-10 code description

Poor Auditory Localization( Central )

## Primary outcomes

### 1

#### Description

Localization Improvement Ventriloquist Effect Improvement Ventriloquist After Effect Improvement

#### Timepoint

Before and after Intervention

#### Method of measurement

By Testing

## Secondary outcomes

### 1

#### Description

Auditory Localization with BBN Stimuli in 12 Azimuth Auditory Localization with Low/ High / BBN Stimuli in 5 Azim

#### Timepoint

Before and after intervention

#### Method of measurement

By testing

## Intervention groups

### 1

#### Description

Intervention group 1 (People with unilateral chronic hearing loss) Each session is called a "learning unit".

Each learning unit consists of 4 sections. In the first part, for ease of localization, the wide-band stimulus has a delay of 1000 milliseconds. On the other hand, four azimuths of 0, 90, 180 and 270 degrees are selected at this stage and the person under training is also told that the sound will be presented in one of these directions. This reduces the difficulty of locating and increases the patient's confidence to continue working. 5 stimuli will be provided from each speaker and the response will be recorded using the GUI. At this stage, the response of the patient is considered to be reinforced in such a way that, if it is correct, a green light on the response recorder will be turned on and feedback will be given. If the answer is wrong, a red light will come on first and then the correct answer will appear on the screen so that the patient can accurately identify the new symptoms. In the following, other azimuth will be presented diagonally. First Azimuth 30, 120, 210 and 300 degrees and next Azimuth 60, 150, 240 and 330 degrees in the mentioned style, the stimuli are presented and the answer related to each angle is recorded in the GUI, thus all 12 speakers Provide the stimulus and the person's response is recorded in 360 degrees. In the second part, all the previous steps are repeated using a stimulus with a delay of 300 milliseconds. In this new exercise, the positioning task becomes more difficult due to the reduction of the stimulus delay. At this stage, several corrective mechanisms have been considered to improve patients' performance. These mechanisms include the following: 1- Following the correct answer, the green light turns on for confirmation. 2- After the wrong answer, the correct location of the speaker is displayed to increase the patient's accuracy 3- The angles that are answered incorrectly are identified and repeated in the next session 4- In angles where the wrong answer is not corrected, by limiting the patient's choices, it helps to increase his accuracy. In the third part, the task of localization becomes more difficult. In this way, the stimuli are presented randomly from the speakers and the listener has no background of the stimulus location and is no longer aware of the possible position of the sound source. In this section, the stimulus duration is 1000 milliseconds. Providing feedback and recording responses is the same as the previous step. In the fourth part, the details of the third part are applied, with the difference that the stimulus delay is 300 milliseconds. This will be the most difficult task for the patient. In total, there will be two weeks for each person and 3 days each week and one learning unit per day. After completing the four sections of the rehabilitation sessions, the patients' last response is recorded as "post-rehabilitation orientation response".

#### Category

Rehabilitation

## 2

#### Description

Intervention group 2: (People with normal hearing) All interventions to the intervention group 1 will be done here as well

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

School of Rehabilitation Sciences, Audiology department

##### Full name of responsible person

Dr.Farnoush Jarollahi

##### Street address

Audiology Department, School of Rehabilitation Sciences, Iran University of Medical Sciences Maddadkaran St., Shahid Nazari St., Mother Square, Mirdamad Blvd, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran.

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

DR. Akram Pourbrbakht

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Pourbakht.a@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**  
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**Full name of responsible person**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

### Deidentified Individual Participant Data Set (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