

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Effect of vowel auditory training on auditory late and behavioral responses of hearing impaired children

#### Protocol summary

##### Summary

**Objectives:** This study is a basic and an applicable one surveying the effect of vowel auditory training on concurrent speech segregation in hearing impaired children. Concurrent segregation is one of the basic components of auditory scene analysis (ASA) and is very important for speech perception. **Design:** Concurrent speech segregation will be measured with auditory late potentials (N1-P2 amplitude and latency) and auditory behavioral tests (reaction time and identification score in percent) for all of the children referred from centers of University of social welfare and rehabilitation sciences. **Setting:** Firstly, auditory late responses and auditory behavioral responses will be recorded from 30 hearing impaired children (Control group=15 and Test group=15). Secondly, vowel auditory training will be conducted for 15 hearing impaired children (Test group) for 3-6 months (2 sessions in per week). Finally, all of the responses will be recorded and compared between both groups. **Participants:** 30 hearing impaired children (4-6 years old) with moderate to severe sensory-neural hearing loss. All of the children have binaural hearing aids. Matching children will be based on age, parent's education level, and birth order. **Measures:** Auditory behavioral tests and auditory late response (N1-P2) will be assessed. **Intervention:** Vowel auditory training will be conducted for 3 months and 6 months. **Main outcomes:** N1-P2 amplitude, N1-P2 latency, Reaction time, Identification score in percent

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013011912174N1**

Registration date: **2013-02-05, 1391/11/17**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-02-05, 1391/11/17

##### Registrant information

###### Name

Hossein Talebi

###### Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2218 0100

###### Email address

h.talebi@uswr.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Investigator

##### Expected recruitment start date

2012-08-22, 1391/06/01

##### Expected recruitment end date

2013-04-20, 1392/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of vowel auditory training on auditory late and behavioral responses of hearing impaired children

##### Public title

Effect of vowel auditory training on concurrent speech segregation of hearing impaired children

##### Purpose

Other

### **Inclusion/Exclusion criteria**

Inclusion criteria; 4-6 years old children with symmetric moderate to severe sensory-neural hearing loss; All of the children have binaural hearing aids; Matching children is conducted on base of age, parent's education level and birth order. Exclusion criteria; Children with profound sensory-neural hearing loss; Children with otitis media, Children with asymmetric hearing loss

### **Age**

From **3 years** old to **6 years** old

### **Gender**

Both

### **Phase**

2

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **30**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **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**

University of social welfare and rehabilitation sciences, Kudakyar Avenue, Daneshjoo Boulevard, Evin

##### **City**

Tehran

##### **Postal code**

1985713834

#### **Approval date**

2012-01-30, 1390/11/10

#### **Ethics committee reference number**

21578

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Hearing loss

### **ICD-10 code**

H90.3

### **ICD-10 code description**

Sensorineural hearing loss, bilateral

## **Primary outcomes**

### 1

#### **Description**

N1-P2 Latency

#### **Timepoint**

Pre intervention, 3 months after intervention, 6 months after intervention

#### **Method of measurement**

milliseconds/ BioLogic system

### 2

#### **Description**

N1-P2 Amplitude

#### **Timepoint**

Pre intervention, 3 months after intervention, 6 months after intervention

#### **Method of measurement**

microvolt/ Biologic system

### 3

#### **Description**

Identification score

#### **Timepoint**

Pre intervention, 3 months after intervention, 6 months after intervention

#### **Method of measurement**

Percent

### 4

#### **Description**

Reaction time

#### **Timepoint**

Pre intervention, 3 months after intervention, 6 months after intervention

#### **Method of measurement**

milliseconds/ timer

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention: Vowel auditory training including vowels ae, er, oo, ah, and ee will be conducted to discriminate and identify those for 3 to 6 months.

#### **Category**

Rehabilitation

## 2

### Description

Control group will receive auditory rehabilitation and vowel auditory training (intervention) will not introduce to this group.

### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

University of social welfare and rehabilitation sciences

##### Full name of responsible person

Mahbubeh Khorshidi

##### Street address

Department of audiology, University of social welfare and rehabilitation sciences, Kudakyar Avenue, Daneshjoo Boulevard, Evin

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research of University of social welfare and rehabilitation sciences

##### Full name of responsible person

Mohammad Shakeri

##### Street address

University of social welfare and rehabilitation sciences, Kudakyar Avenue, Daneshjoo Boulevard, Evin

##### City

Tehran

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Vice chancellor for research of University of social welfare and rehabilitation sciences

##### Proportion provided by this source

100

##### Public or private sector

*empty*

##### Domestic or foreign origin

*empty*

##### Category of foreign source of funding

*empty*

##### Country of origin

##### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

University of social welfare and rehabilitation sciences

#### Full name of responsible person

Hossein Talebi

#### Position

PhD candidate

#### Other areas of specialty/work

#### Street address

Department of audiology, University of social welfare and rehabilitation sciences, Kudakyar Avenue, Daneshjoo Boulevard, Evin

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ht6023@gmail.com

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

University of social welfare and rehabilitation sciences

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Hossein Talebi

#### Position

PhD candidate of audiology

#### Other areas of specialty/work

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#### Web page address

## Person responsible for updating data

### Contact

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

*empty*

### Study Protocol

*empty*

### Statistical Analysis Plan

*empty*

### Informed Consent Form

*empty*  
**Clinical Study Report**  
*empty*  
**Analytic Code**

*empty*  
**Data Dictionary**  
*empty*