

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### The effect of hearing preservation education on listening behavior among students using personal music players

#### Protocol summary

##### Study aim

The level of knowledge about noise induced hearing loss should be evaluated among high school students in Tehran. Then, the effect of hearing protection education on behavioral changes regarding listening to recreational noise will be examined.

##### Design

This pre- post study will be conducted on 300 high school students considering inclusion criteria. Schools will be chosen randomly from different regions of city. One class in each grade will be chosen randomly.

##### Settings and conduct

Schools will be selected randomly from different regions of Tehran. In the first stage, one questionnaire will be developed to assess the hearing habits, the level of knowledge about the consequences of hearing loss, and the leading role of hearing protection in preventing of hearing loss. In this regard, one compact disc will be provided for educational purposes, which will include information about the source of noise and its effect on auditory system, the epidemiology of noise induced hearing loss and its mechanism, its symptoms and some recommendations for the prevention of NIHL. In addition, in order to confirm the suitability of the developed questionnaire and the educational materials with the age of the students, project executives will interview school officials. Simultaneously, different types of auditory problems such as mild, moderate, severe, high frequency and low frequency hearing loss, tinnitus and autophonia will be simulated as an audio file through Cool Edit software. In the second stage, the students' preferential listening levels will be evaluated. For this purpose, the level of loudness will be estimated by adjustment method, in which students will be asked to listen to five different types of one minute music and adjust their desired volume. These music will be presented by a portable personal music player with insert receiver. Then, the intensity of music will be measured by 2cc coupler. In following, the developed questionnaire will be

completed before and after education and its information will be collected. The ANOVA analysis will be used to compare the results of questionnaire and preferential loudness before and after education.

##### Participants/Inclusion and exclusion criteria

Since normal hearing is one of the inclusion criteria, Otoscopy and screening audiometry will be done for all students. Only students whose parents had already signed the consent letter to participate are included in the study. It should be noted that if the student or his/her parents are dissatisfied with continuation of the work, this person will rule out.

##### Intervention groups

In this study, a series of 30-minute group sessions have been considered in which students are taught through oral presentation with power points and simulated audio files. Behavioral evaluation of preferential loudness will be evaluated in three stage: before education, immediately after education and one month later.

##### Main outcome variables

The intensity of headphone output, the level of knowledge about consequences of hearing loss and tinnitus, the level of knowledge about hearing protection in noisy environments, and the level of inclination to prevent auditory sense from noisy environments are considered as research variables. In this regard, 2 cc coupler embedded in SLM will be used to measure the mean intensity of headphone output. Furthermore, the five-point Likert scale questionnaire, from lack of awareness to much awareness, will be applied to assess the level of knowledge about consequences of hearing loss and tinnitus and the level of knowledge about hearing protection in noisy environments. The level of interest in preventing ears in noisy environments will be evaluated by Likert's five-point scale, from disinclination to much inclination. Behavioral evaluation of preferential loudness will be evaluated in three stage: before education, immediately after education and one month later.

## General information

### Reason for update

### Acronym

### IRCT registration information

IRCT registration number: **IRCT20151005024360N3**

Registration date: **2018-01-03, 1396/10/13**

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

Last update: **2018-01-03, 1396/10/13**

Update count: **0**

### Registration date

2018-01-03, 1396/10/13

### Registrant information

#### Name

Akram Pourbakht

#### Name of organization / entity

#### Country

Iran (Islamic Republic of)

#### Phone

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#### Email address

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### Recruitment status

#### Recruitment complete

### Funding source

Iran University of Medical Sciences

### Expected recruitment start date

2017-12-01, 1396/09/10

### Expected recruitment end date

2018-12-01, 1397/09/10

### Actual recruitment start date

empty

### Actual recruitment end date

empty

### Trial completion date

empty

### Scientific title

The effect of hearing preservation education on listening behavior among students using personal music players

### Public title

The effect of hearing preservation education on listening behavior of students

### Purpose

Prevention

### Inclusion/Exclusion criteria

#### Inclusion criteria:

normal hearing

#### Exclusion criteria:

Not be in favor of entering the study

### Age

From **15 years** old to **18 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **300**

### Randomization (investigator's opinion)

N/A

### Randomization description

Schools will be chosen by simple randomization. The way of randomization in choosing a class at each grade is by drawing a number.

### 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 Campus, Hemmat freeway, next to Milad tower, Tehran,

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۳۹۶۱۴۵۳۵

#### Approval date

2017-05-21, 1396/02/31

#### Ethics committee reference number

IR.IUMS.REC 1396.0637

## Health conditions studied

### 1

#### Description of health condition studied

Noise effects on inner ear

#### ICD-10 code

H83.3X3

#### ICD-10 code description

Noise effects on inner ear, bilateral

## Primary outcomes

### 1

#### Description

The intensity of headphone output

**Timepoint**

before, immediately and a month after education

**Method of measurement**

SLM

**2****Description**

the level of knowledge about consequences of hearing loss and tinnitus

**Timepoint**

before, immediately and a month after education

**Method of measurement**

questionnaire

**3****Description**

the level of knowledge about hearing protection in noisy environments

**Timepoint**

before, immediately and a month after education

**Method of measurement**

questionnaire

**4****Description**

the level of interest in preventing ears in noisy environments

**Timepoint**

before, immediately and a month after education

**Method of measurement**

questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

In this study, a series of 30-minute group sessions have been considered in which students are taught through oral presentation with power points and simulated audio files. There is no control group at this study.

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

High schools in different regions of Tehran

**Full name of responsible person**

Marjan Soleymani

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hi.roshangaran@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Malakouti

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Hemmat highway, Next to Milad Tower

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research@iums.ac.ir

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**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**

Akram Pournabakht

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Audiology

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Associate Professor, Head of Department

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**Full name of responsible person**

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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