Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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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
۱۴۴۹۶۱۴۵۳۵
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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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Hemmat highway, Next to Milad Tower
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Tehran
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Web page address
http://vcr.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
Iran University of Medical Sciences
Full name of responsible person
Akram Pourbakht
Position
Associate professor
Latest degree

Ph.D.
Other areas of specialty/work
Audiology
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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