Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigation of the effect of education on workers' noise annoyance

Protocol summary

Study aim

GENERAL OBJECTIVE : Determination of the effect of education on workers noise annoyance rate in intervention and control groups SPECIFIC OBJECTIVES: 1- Determining and comparing the effect of education on workers noise annoyance rate in two groups of intervention and control in relation to noise and its effects before and after intervention. 2- Determining and comparing the effect of education on The average score of workers' knowledge, attitude and performance in the two groups of intervention and control in relation to noise and its effects before and after intervention. 3- Determining the relationship between demographic factors and noise annoyance.

Design

Clinical trials with intervention and control group,Randomized ,Single-Blind

Settings and conduct

On first shift, those parts of the factory which are exposed to noise over 85 dB, 85 workers are randomly chosen by draw, After completing the questionnaires,based on pretest results, designing of educational intervention and media will be required.In the same way, of the workers of the other shift (who do not usually contact each other), 85 people will be selected as a control group.After the training classes for the intervention group workers, two months after the intervention, both groups are followed up, and questionnaires are completed again for them.

Participants/Inclusion and exclusion criteria

inclusion criteria: 1- working in the Pinak manufacturing co. 2- exposure to noise over 85 dB 3- working experience of at least 1 year 4- no hearing loss above 25 dB 5- agreeing to enter the study. Exclusion criteria : 1- Unwillingness to continue cooperation

Intervention groups

1- Intervention group: Includes people in the Shift A that receive educational intervention. 2- Control group Includes people in the Shift B that do not receive educational intervention.

Main outcome variables

knowledge, attitude and practice and noise annoyance

General information

Reason for update

Acronym

KAP

IRCT registration information

IRCT registration number: **IRCT20151103024859N2**
Registration date: **2018-11-15, 1397/08/24**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-15, 1397/08/24**
Update count: **0**

Registration date

2018-11-15, 1397/08/24

Registrant information

Name
Iraj alimohammadi
Name of organization / entity
Iran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigation of the effect of education on workers' noise annoyance

Public title
Investigating of the effect of education on workers' noise annoyance

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Work in Pinak manufacturing co. Exposure to sound greater than 85 dB Work experience at least 1 year No hearing loss above 25 dB Agree to enter the study

Exclusion criteria:
Lack of employment in Pinak manufacturing co. Exposure to noise less than 85 dB Work experience less than 1 year Hearing loss greater than 25 dB Unwillingness to enter the study

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **170**

Randomization (investigator's opinion)
Randomized

Randomization description
At first, for blinding,groups 1 and 2 were selected from two different shifts. On both shifts, the names of the people were first sorted according to their staff numbers. Then by using extant software in the internet which is used for random work, the first groups, on first shift workers including 103 people 85 ones are simply randomly selected without any alternatives. Also, the second group, on second shift workers, which consist of 113 people, was randomly assigned to 85 individuals. Then the numbers were matched with the staff numbers of the workers, and the samples were selected. The intervention and control groups are chosen by tossing up. The letters A and B were attributed to them. in this way groups A, the first group ,is chosen as the intervention group and group B, the second group , is chosen as the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The two groups don’t interfere with each other. 85 of Shift 1 and 85 of Shift 2 are selected. The control group is not informed about the existence of the training.

Placebo
Not used

Assignment
Parallel

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, Hemat Highway next to Milad Tower,Tehran

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2018-01-01, 1396/10/11

Ethics committee reference number
IR.IUMS.REC1396.9511139003

Health conditions studied

1

Description of health condition studied
noise annoyance due to occupational exposure to noise

ICD-10 code
Z57.0

ICD-10 code description
Occupational exposure to noise

Primary outcomes

1

Description
noise annoyance, score of ISO 15666 questionnaire

Timepoint
Measuring the noise annoyance (Before intervention) and 2 months after the intervention

Method of measurement
ISO 15666 questionnaire

2

Description
Knowledge, information and understanding about noise and hearing protection devices are used.

Timepoint
Measuring knowledge (Before intervention) and 2 months after the intervention

Method of measurement
Researcher-made questionnaire Knowledge Attitude Practices study related to noise

3

Description
Attitude - A more or less constant condition of the mental system that reflects a person's stimulating sensation of something like hearing loss.
Timepoint
Measuring attitude (Before intervention) and 2 months after the intervention
Method of measurement
Researcher-made questionnaire Knowledge Attitude Practices study related to noise

4

Description
Practice - The perception and understanding of the worker himself
Timepoint
Measuring practice (Before intervention) and 2 months after the intervention
Method of measurement
Researcher-made questionnaire Knowledge Attitude Practices study related to noise

5

Description
Training - The purpose of education is an activity that aims to increase the Knowledge of individuals with a view to changing attitudes and practices.
Timepoint
Measurement of knowledge ,attitude and practice (before intervention) and 2 months after intervention
Method of measurement
Researcher-made questionnaire Knowledge Attitude Practices study related to noise

Secondary outcomes

1

Description
noise annoyance, score of ISO 15666 questionnaire
Timepoint
Measuring the noise annoyance (Before intervention) and 2 months after the intervention
Method of measurement
ISO 15666 questionnaire

Intervention groups

1

Description
intervention group :On first shift; those parts of the factory which are exposed to noise over 85 dB, 85 workers are randomly chosen by draw, based on the workers numbers.After describing the procedure and purpose of research, their consents are filled out. If the worker doesn’t want to participate in the study, sampling will continue until the sampling size is completed in the intervention group.After completing the questionnaires (the knowledge, attitude and practice questionnaire, noise annoyance questionnaire), audiometry is done by the researcher in the studied sampler.After performing a pretest, the data is entered into the statistical software.Based on pretest results, designing of educational intervention and media will be required.Educational intervention that is likely to be in the form of 3 to 4 sessions of group discussion and lectures.After the training classes for the intervention group workers, two months after the intervention, both groups are followed up, and questionnaires are completed again for them.In the same way, of the workers of the other shift (who do not usually contact each other), 85 people will be selected as a control group.
Category
Diagnosis

2

Description
control group : Among other shift workers who are exposed to noise over 85 dB, 85 workers are randomly chosen by draw.The choice is based on their worker numbers.Similar to the intervention group, questionnaires (knowledge, attitude, practice questionnaire, noise annoyance questionnaire) are completed by selected workers. Audiometry is done by the researcher in the studied sampler.After the pretest, the information of both groups is entered into the statistical software for designing is entered into the statistical software for designing of the educational intervention and the required media. The control group doesn’t receive any training.Two months later, the control group will completed the relevant questionnaires, again.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
PINAK Manufacturing co.
Full name of responsible person
Manouchehr Takrousta
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Sponsors / Funding sources

1

Sponsor
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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
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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