

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Investigating the effect of music on the cognitive performance and task performance of female operators in the assembly operation of a medical equipment manufacturing company in Isfahan

#### Protocol summary

##### Study aim

Investigating the effect of music on the cognitive performance and task performance of female operators in the assembly operation of a medical equipment manufacturing company in Isfahan

##### Design

All the evaluations in this study will be done on all study participants in one work shift and all people will be compared in different modes of playing music and not playing music.

##### Settings and conduct

The present research will be conducted among female assemblers working in a medical equipment manufacturing industry (serum set) in Isfahan city. In this study, fatigue and sleepiness using the Flicker Fusion device, cognitive performance (working memory, sustained attention) using cognitive tests such as CPT, N-Back and measuring task performance by counting the number of products in two modes of the music section and Failure to play music will be assessed.

##### Participants/Inclusion and exclusion criteria

Conditions for entering the study: People do not have a history of diseases affecting cognitive function such as psychological diseases. Before entering the study, people should not take drugs that affect cognitive function, such as sleeping pills. People should not consume caffeine 8 hours before the test. People should have enough rest and sleep the night before the test. People have general health. People are not in their menstrual period. People must consent to participate in the study Conditions for withdrawing from the study: Dissatisfaction and declaration of withdrawal from continuing to participate in the study for any reason

##### Intervention groups

In this research, only one group of available female operators (including 81 people) will be studied in two modes of playing music and not playing music.

#### Main outcome variables

Working memory, sustained attention and task performance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231220060479N1**

Registration date: **2024-01-01, 1402/10/11**

Registration timing: **prospective**

Last update: **2024-01-01, 1402/10/11**

Update count: **0**

##### Registration date

2024-01-01, 1402/10/11

##### Registrant information

##### Name

Mahnaz Shakerian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 3266

##### Email address

mahnazshakerian@hlth.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-02-20, 1402/12/01

##### Expected recruitment end date

2024-09-22, 1403/07/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of music on the cognitive performance and task performance of female operators in the assembly operation of a medical equipment manufacturing company in Isfahan

**Public title**

Effect of music on the cognitive performance

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

People do not have a history of diseases affecting cognitive function such as psychological diseases. Before entering the study, people should not take drugs that affect cognitive function, such as sleeping pills. People should not consume caffeine 8 hours before the test. People should have enough rest and sleep the night before the test. People have general health. People are not in their menstrual period. People must consent to participate in the study.

**Exclusion criteria:**

Dissatisfaction and declaration of withdrawal from continuing to participate in the study for any reason

**Age**

From **18 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **81**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features**

The current research is a cross-sectional-descriptive analytical study that will be conducted among 95 female assemblers working in the medical equipment manufacturing industry (serum sets) in Isfahan city. In this industry, personnel work in 2 shifts and each shift is 8 hours long in the assembly unit. Data sampling will be collected using the method of direct observation of the work process, conducted by the research team, interviews of assembly personnel and unit supervisors, questionnaires and cognitive tests. The steps of the research will be carried out as follows:1. Collecting demographic information about the participants2.

Evaluation of introversion/extroversion of the participants using the NEO-FFI questionnaire3. Evaluation of fatigue and sleepiness using the Flicker Fusion device4. Evaluation of cognitive status using cognitive tests such as CPT, N-Back5. Measurement of task performance by counting the number of products and checking the assembly error of parts by observing and collecting industry quality control information.All the tests mentioned above will be done in one work shift and in different modes of playing music and not playing music.Music will be used as an intervention in this study and will be played through a loudspeaker with the same volume for all participants in the music effect test stage. Investigating the effect of music on the cognitive performance and task performance of people during a work shift, music will be played during a work shift and throughout the duration of the work shift.Note 1: Considering the past studies on the study of the effect of music and the selection of classical types of music, in this study also classical music will be used.Note 2: The type of music will be selected without words and in a non-aggressive manner, taking into account the culture and beliefs of the society, with an emphasis on the music approved by the Ministry of Culture and Islamic Guidance.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences Hezar Jerib street, Isfahan, Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Approval date**

2023-06-19, 1402/03/29

**Ethics committee reference number**

IR.MUI.RESEARCH.REC.1402.107

**Health conditions studied****1****Description of health condition studied**

Cognitive performance (working memory, sustained attention) of female operators in the assembly operation of a medical equipment manufacturing company in Isfahan

**ICD-10 code**

## ICD-10 code description

## Primary outcomes

### 1

#### Description

Cognitive performance (working memory, sustained attention)

#### Timepoint

In this study, variables of working memory and sustained attention will be evaluated at the beginning and end of the work shift.

#### Method of measurement

Using working memory by active memory test (N-Back) and sustained attention using Continuous Performance Test (CPT)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In this group, all female operators working in the desired industry are evaluated in terms of cognitive performance in the music playing mode at the beginning and end of the shift work, and as a result, their performance at the beginning and end of the shift is compared.

#### Category

N/A

### 2

#### Description

Control group: In this group, all the female operators working in the desired industry are evaluated in terms of cognitive performance at the beginning and end of the shift without playing music, and as a result, their performance at the beginning and end of the shift is compared.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mehrtaab Jey Company

##### Full name of responsible person

Melika Abbasi

##### Street address

41 East Bahar Street, Niloufar Street, Sarooshbadran Industrial Zone, Isfahan.

##### City

Isfahan

#### Province

Isfahan

#### Postal code

8166186418

#### Phone

+98 31 3855 3234

#### Email

mehrtebheiofficial@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Dr Gholamreza Asgari

##### Street address

Isfahan University of Medical Sciences, Isfahan, Iran

##### City

Isfahan

##### Province

Isfahan

##### Postal code

81746-73461

##### Phone

+98 31 3668 8628

##### Email

mahnazshakerian@hlth.mui.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

##### Full name of responsible person

Mahnaz Shakerian

##### Position

Assisstanat professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Ergonomics

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**City**

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**Province**

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**Postal code**

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**Phone**

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**Email**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mahnaz Shakerian

**Position**

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Ph.D.

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**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mahnaz Shakerian

**Position**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information.

**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**

Not applicable

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Not applicable