Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A comparative study of the effect of Iranian and Western classical music on some physiological parameters and the level of consciousness of children aged 1 -6 years admitted to the internal pediatric intensive care units

Protocol summary

Study aim
Comparative determination of the effect of Iranian classical music and Western classical music on some physiological symptoms and level of consciousness of children aged 1-6 years admitted to the pediatric intensive care units

Design
This study is a parallel randomization clinical trial and the intervention groups (there are 2 groups) and the control group are to be investigated simultaneously. In total, information about 45 people will be collected and reviewed. (each group 15 people)

Settings and conduct
The place: Pediatric internal intensive care unites of Namazi Hospital. And after selecting the samples and randomizing them, Iranian classical music will be played for one group and Western classical music will be played for one group , and no music will be played for the control group. 5 minutes before the start of the music. Treatment of physiological symptoms (heart rate and blood oxygen saturation level) will be recorded, and the patient's level of consciousness will be determined using the Glasgow Coma Scale. In the 15th minute and also 5 minutes after the intervention, the above information will be recorded again.

Participants/Inclusion and exclusion criteria
Entry: The child must be 1-6 years old and be intubated, and the guardian must have the necessary consent and motivation for their child's participation in the research. Failure to enter: due to the patient's unstable hemodynamic conditions, we cannot play music, and the patient dies.

Intervention groups
In this study, we have three intervention groups. Group 1: Iranian classical music Group 2: Western classical music It will be played through a bluetooth headset and group 3: (control group) and no music will be played. The duration of music playing will be 2 times a day (10-11 in the morning, 15-16 in the evening) and each time will be 30 minutes..

Main outcome variables
Physiological symptoms, level of consciousness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230921059486N1**
Registration date: **2023-10-31, 1402/08/09**
Registration timing: **prospective**

Last update: **2023-10-31, 1402/08/09**
Update count: **0**

Registration date
2023-10-31, 1402/08/09

Registrant information

Name
Elham Ghasemi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2023-11-11, 1402/08/20

Expected recruitment end date

2023-12-11, 1402/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effect of Iranian and Western classical music on some physiological parameters and the level of consciousness of children aged 1 -6 years admitted to the internal pediatric intensive care units

Public title

the effects of music therapy in children

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

The child must be 1-6 years old Be hospitalized in the internal special care departments of Namazi Hospital for children At least 30 minutes have passed since the last therapeutic intervention of the caregiver The child should be intubated Parents should have the necessary satisfaction and motivation for their child's participation in the research Do not perform any procedures on the patient while listening to music At least 48 hours have passed since the child was intubated in the intensive care unit

Exclusion criteria:

Due to unstable hemodynamic conditions or cardiac arrest of the patient, we cannot play the music at the appointed time During music therapy, he needs therapeutic and diagnostic procedures The patient suffers brain death during the study Death of the patient

Age

From **1 year** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be done by the permutation block method in 4 blocks of 9 with Random Allocation software. The researcher will not know what music is currently playing.

Blinding (investigator's opinion)

Single blinded

Blinding description

The researcher will select the samples and the research assistant will play the music and the researcher will not know about its type.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Fars University of Medical Sciences and Medical Services

Street address

SHiraz., Zand Ave., In front of Palestine Street., Central Building of Shiraz University of Medical Sciences

City

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Province

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7376144554

Approval date

2023-09-20, 1402/06/29

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1402.063

Health conditions studied

1

Description of health condition studied

Patients admitted to the intensive care unit of Namazi Hospital

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Physiological symptoms (heart rate - blood oxygen saturation level)

Timepoint

5 minutes before the start of the intervention, 15 minutes after the start of the intervention the and 5 minutes after the end of the intervention.

Method of measurement

By pulse oximeter model PO16

2

Description

level of consciousness

Timepoint

5 minutes before the start of the intervention, 15 minutes after the start of the intervention the and 5 minutes after the end of the intervention.

Method of measurement

Glasgow coma scale(GCS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first intervention group: the group for whom classical Iranian music will be played

Category

N/A

2

Description

Intervention group: The second intervention group: the group for whom western classical music will be played.

Category

N/A

3

Description

Control group: No music will be played for them.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi hospital

Full name of responsible person

Elham ghasemi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Research Vice President of Shiraz University of Medical Sciences

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Neda Jamalimoghadam

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associate professor

Latest degree

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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available