Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of nature-based sounds on nausea, vomiting, and stress in Acute myeloid leukemia patients undergoing chemotherapy

Protocol summary

Study aim

Determining the effect of nature-based sounds on nausea, vomiting and stress in acute myeloid leukemia patients undergoing chemotherapy

Design

The current study is a clinical trial with an intervention and control group, employing a double-blind, randomized design on 52 patients. SPSS software will be used for data analysis.

Settings and conduct

Patients in the intervention group will listen to the sounds of nature in their rooms for 30 minutes each time using headphones. The study tools will be completed by the participants before the intervention and every day during the chemotherapy period. Patients in the control group will receive usual care and wear headphones without music.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People who have recently been diagnosed with acute myeloid leukemia (new cases) Patients who will undergo chemotherapy for the first time. The uniformity of the chemotherapy protocol of the patients. People who are fully conscious. The patient should not be in a critical state of health that would interfere with listening to music. Not smoking at the present time. No drug addiction. Not suffering from respiratory and mental diseases diagnosed by a doctor. Be able to read and write. Exclusion criteria: The patient's unwillingness to continue to cooperate in the research Creating a critical situation that threatens the patient's life death of the patient

Intervention groups

Intervention group: playing nature-based sounds through headphones and determining its effect on nausea, vomiting and stress Control group: receiving routine interventions and receiving headphones without playing sound and determining its effect on nausea, vomiting and stress

Main outcome variables

Independent variable: Nature-based sounds Dependent variables: nausea, vomiting, stress

General information

Reason for update

Changes have been made in the proposal after obtaining the code of ethics from Ahvaz Jundishapur University of Medical Sciences, which should be applied in the registered trial as well.

Acronym

IRCT registration information

IRCT registration number: **IRCT20230612058466N1**
Registration date: **2023-07-01, 1402/04/10**
Registration timing: **prospective**

Last update: **2026-04-15, 1405/01/26**
Update count: **1**

Registration date

2023-07-01, 1402/04/10

Registrant information

Name

Parisa Sheini-Jaberi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8070

Email address

sheinijaberi-p@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date
2024-06-21, 1403/04/01
Actual recruitment end date
2025-03-15, 1403/12/25
Trial completion date
2025-03-15, 1403/12/25

Scientific title
The effect of nature-based sounds on nausea, vomiting, and stress in Acute myeloid leukemia patients undergoing chemotherapy

Public title
The effect of nature-based sounds on nausea, vomiting, and stress
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Consent to enter the study Patients with recently diagnosed acute myeloid leukemia. (New cases) Patients who will undergo chemotherapy for the first time. Patients who have the same chemotherapy protocol. Patients who are fully conscious and not under airway intubation. Patients who are not in a critical health condition and listening to music is safe for them. No current smoking No drug addiction Patients who do not have respiratory and psychological diseases diagnosed by a physician. Ability to read and write Patients who are at least 18 years old.
Exclusion criteria:
Patients undergoing outpatient chemotherapy. Patients with hearing impairment.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **114**
Actual sample size reached: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
The method of assigning the intervention to people is randomly and by the method of randomized permutation blocks with random block sizes of 4, 6 and 8 (using the table related to random permutations). The randomization list is prepared by a statistician. The intervention used in this research is allocated according to the randomized list by a person outside the study who is not aware of the research objectives and according to the corresponding codes in the sealed envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
After selecting the samples, none of the sampled people will know about the randomization and the process of allocation to the groups. The researcher is given a pre-prepared list and enters the patients into the study in the order of the list numbers. Similar headphones are given to the patients of both groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research ethics committee of Ahvaz Jundi Shapur University of Medical Sciences
Street address
Golestan St.
City
Ahvaz
Province
Khouzestan
Postal code
6135733331
Approval date
2023-05-27, 1402/03/06
Ethics committee reference number
IR.AJUMS.REC.1402.125

Health conditions studied

1

Description of health condition studied
Acute myeloid leukemia
ICD-10 code
C92.0
ICD-10 code description
Acute myeloid leukemia

Primary outcomes

1

Description
The score of the Rhodes Nausea and Vomiting Severity Questionnaire is less than 9. The DASS-21 score for stress is less than 19.
Timepoint
Before starting the intervention and then every day for 7 days
Method of measurement
Rhodes questionnaire to measure the severity and frequency of nausea and vomiting; DASS-21

questionnaire to measure stress

Secondary outcomes

1

Description
The quality of life score of the patients is at a good level.
Timepoint
Before starting the intervention; 7 days and 30 days after the start of the intervention
Method of measurement
Quality of Life Questionnaire-Core 30 (QLQ-C30)

Intervention groups

1

Description
Intervention group: An MP3 device containing different sounds based on nature will be provided to the patients of the intervention group. These sounds include: the sound of birds, the sound of rain, the sound of a stream, the sound of a waterfall, walking in the forest. This will be done for 7 days. During the chemotherapy period, patients will be placed on their bed in whatever position they feel more comfortable (semi-sitting or supine position) and will listen to the set of sounds using headphones for 30 minutes in their rooms. The sound of headphones (25-50 dB) is adjusted so that it is satisfactory for the person and does not cause discomfort and ear irritation.
Category
Prevention

2

Description
Control group: Control group: An MP3 device without any sound will be provided to patients in the control group. This will be done for 7 days. During the chemotherapy period, patients will be placed on their bed in whatever position they feel more comfortable (semi-sitting or supine position) and will put headphones in their ears without music for 30 minutes in their rooms. All control group participants will receive usual care.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Baghaei-2 Hospital
Full name of responsible person
Bijan Keikhaei
Street address
Golestan highway, Bagai square
City
Ahvaz
Province
Khouzestan
Postal code
6138933333
Phone
+98 61 3375 0410
Email
keikhaei-b@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehrnoosh Zakerkish
Street address
Golestan St.
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3336 1544
Email
zakerkish-m@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Shahram Molavynejad
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery

Street address
Golestan St.
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8070
Email
shahrambaraz@ajums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Shahram Molavynejad
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Golestan St.
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8070
Email
shahrambaraz@ajums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Parisa Sheini-Jaberi
Position
lecturer
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Golestan St.
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8070
Email
psheinijaberi@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The study report will be provided to the University of Medical Sciences. Also, the study will be published as an article.
When the data will become available and for how long
After the approval of the thesis
To whom data/document is available
The results of the study will be accessible to the researchers and the target group.
Under which criteria data/document could be used
If necessary, the unidentifiable file in SPSS software format will be provided to Jundishapur University of Medical Sciences.
From where data/document is obtainable
Central Library of Jundishapur University of Medical Sciences, Ahvaz; Library of the Faculty of Nursing and Midwifery; Responsible author and supervisor (Parisa Sheini-Jaberi: psheinijaberi@yahoo.com)
What processes are involved for a request to access data/document
send messages by e-mail; Refer to libraries
Comments