

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### The Effectiveness of Music Therapy on Pain Intensity, Perceived Stress and Aggression

#### Protocol summary

##### Summary

(1) Objectives :The aim of this study is to evaluate the effectiveness of music therapy on pain intensity, perceived stress and aggression of Leukemia youth in Shafa hospital in Ahvaz City. (2) Design : The study will be randomized controlled trial without blinding. The research designed as experimental with pretest, posttest and control group. (3) Setting and conduct: The sample will be 30 (15 in the control group and 15 in experimental group) subjects of patients with leukemia whom will selected via simple random sampling. (4)Inclusion Criteria: To have Leukemia; to be content to participate; were alert and oriented to person and place; Mastered in Persian Language, Exclusion Criteria: any significant hearing or visual impairments; any prior cognitive impairment (e.g., head injury, history of psychosis, brain metastases, experiencing a severe psychotic episode); immobility; major depression; allergy to sound or had the voice sensitivity of epilepsy; severe high blood pressure or heart disease or if sedated for their treatment or not preferred to music listening. (5) Intervention: First the two groups will check. Then the experimental group will expose to music therapy for 18 sessions, each session lasted 60 minutes. The control group receive none. After that the two groups will check again.. Finally the follow-up was performed after one month. (6) Main outcome measures (variables): Short-form MC Gill Pain Questionnaire (MPQ), Perceived Stress Scale (PSSQ-14) and Ahvaz Aggression Questionnaire (AAGQ) will be used as data source . Analysis of covariance (MANCOVA) is the main statistical procedure to analyze data.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016121026390N10**

Registration date: **2017-11-01, 1396/08/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-11-01, 1396/08/10

##### Registrant information

###### Name

Ehsan Ghaedi

###### Name of organization / entity

Ahvaz Jundishapoor ,University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3374 3285

###### Email address

ghaedi.e@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ahvaz Jundishapour University of Medical Sciences

##### Expected recruitment start date

2015-12-08, 1394/09/17

##### Expected recruitment end date

2016-12-21, 1395/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effectiveness of Music Therapy on Pain Intensity, Perceived Stress and Aggression

##### Public title

The Effectiveness of Music Therapy on Pain, Stress and

Aggression

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion Criteria: To have Leukemia; to be content to participate; were alert and oriented to person and place; Mastered in Persian Language, Exclusion Criteria: any significant hearing or visual impairments; any prior cognitive impairment (e.g., head injury, history of psychosis, brain metastases, experiencing a severe psychotic episode); immobility; major depression; allergy to sound or had the voice sensitivity of epilepsy; severe high blood pressure or heart disease or if sedated for their treatment or not preferred to music listening

**Age**

From **12 years** old to **18 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

1

**Registry name**

**Secondary trial Id**

**Registration date**

2017-11-21, 1396/08/30

2

**Registry name**

**Secondary trial Id**

**Registration date**

2017-11-21, 1396/08/30

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ahvaz Jundishapur University of Medical Sciences  
Ethics Committee

**Street address**

Ahvaz Jundishapur University of Medical Sciences,  
Farvardin St., Golestan Blvd, Ahvaz

**City**

Ahvaz

**Postal code**

**Approval date**

2016-01-21, 1394/11/01

**Ethics committee reference number**

IR.AJUMS.REC.1394.595

**Health conditions studied**

1

**Description of health condition studied**

Pediatric Leukemia

**ICD-10 code**

C91.0

**ICD-10 code description**

Acute Lymphoblastic Leukemia

**Primary outcomes**

1

**Description**

pain intensity

**Timepoint**

before and after of intervention

**Method of measurement**

Short-form MC Gill Pain Questionnaire (sf-MPQ)

2

**Description**

Perceived stress

**Timepoint**

before and after of intervention

**Method of measurement**

Perceived Stress Scale (PSSQ-14)

**Secondary outcomes**

1

**Description**

Aggression

**Timepoint**

before and after the intervention

**Method of measurement**

Ahvaz Aggression Questionnaire (AAGQ)

**Intervention groups**

1

**Description**

Intervention: The experimental group listened to music for 30 min for 18 sessions;

**Category**

Behavior

**2**

**Description**

Control: the control group rested in bed in same time

**Category**

Behavior

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shafa Hospital

**Full name of responsible person**

Dr Jaseb Oncologist

**Street address**

Shafa Hospital, Farvardin Street, Golestan Bolvard, Ahwaz City

**City**

Ahwaz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Ahwaz Jundishapur University of Medical Science

**Full name of responsible person**

Sharif Makhmalzadeh

**Street address**

Ahwaz Jundishapur University of Medical Science, Farardin St., Golestan Blvd, Ahwaz

**City**

Ahwaz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research, Ahwaz Jundishapur University of Medical Science

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Research Center of Thalassemia and Hemoglobinopathy, Health Research Institute, Ahwaz Jundishapur Un

**Full name of responsible person**

Kaveh Jaseb

**Position**

MD, Oncologist

**Other areas of specialty/work**

**Street address**

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**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University, Ahwaz Branch

**Full name of responsible person**

Farah Naderi

**Position**

Ph.D

**Other areas of specialty/work**

**Street address**

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**Person responsible for updating data**

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**Name of organization / entity**

Research Center of Thalassemia and Hemoglobinopathy, Health Research Institute, Ahwaz Jundishapur Un

**Full name of responsible person**

Ehsan Ghaedi

**Position**

-

**Other areas of specialty/work**

**Street address**

Shafa Hospital, Farvardin St, Golsetan Blvd, Ahvaz

City

**City**

Ahvaz

**Postal code**

**Phone**

00

**Fax**

**Email**

**Web page address**

**Sharing plan**

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*