Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Ahwaz 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

befor and after of intervention

Method of measurement

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

2

Description

Percieved stress

Timepoint

befor and after of intervention

Method of measurement

Perceived Stress Scale (PSSQ-14)

Secondary outcomes

1

Description

Aggression

Timepoint

befor 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

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur University of Medical Science

Full name of responsible person

Sharif Makhmalzadeh

Street address

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

City

Ahvaz

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, Ahvaz 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, Ahvaz Jundishapur Un

Full name of responsible person

Kaveh Jaseb

Position

MD, Oncologist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University, Ahvaz Branch

Full name of responsible person

Farah Naderi

Position

Ph.D

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Research Center of Thalassemia and Hemoglobinopathy, Health Research Institute, Ahvaz 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

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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