

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Aug 2026

### Effect of music therapy on pain and anxiety in children with Leukemia undergoing Bone Marrow Aspiration and Lumbar Puncture

#### Protocol summary

##### Summary

The aim of this study is to determine effect of music therapy on pain and anxiety in children with leukemia undergoing bone marrow aspiration and lumbar puncture. This study is a randomized clinical trial which includes 50 children(aged 6 to 12 years) with leukemia admitted for bone marrow aspiration and lumbar puncture in Pediatric hospital in Kermanshah and selected for the study by eligibility criteria, and assigned to intervention group (n=25) or control group (n=25) by randomized blocking method. The participants in the intervention group listened to childish music through headphone 30 minutes before and during the aggressive procedure, while the control group received routine care. Anxiety and pain scores as the primary outcomes and vital signs include respiratory rate, heart rate, blood pressure and arterial oxygen saturation as secondary consequences measured before, during and after the intervention. Survey's data collected by Revised Children's Manifest Anxiety scale (RCMAS), Wong-Baker faces pain scale, behavioral pain scale (FLACC) and questionnaire about personal information- medical history.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016052528074N1**

Registration date: **2017-02-02, 1395/11/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-02-02, 1395/11/14

##### Registrant information

##### Name

Nasrin Ghanbari

##### Name of organization / entity

Tehran University of Social Welfare and Rehabilitation Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2218 0083

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, University of Social Welfare and Rehabilitation sciences

##### Expected recruitment start date

2016-04-10, 1395/01/22

##### Expected recruitment end date

2016-09-05, 1395/06/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of music therapy on pain and anxiety in children with Leukemia undergoing Bone Marrow Aspiration and Lumbar Puncture

##### Public title

Effect of music on pain and anxiety

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: aged 6 to 12 years; satisfaction and willingness of parents and children to cooperate; Having acute leukemia; lack of mental, visual and hearing

impairment; lack of analgesic and anti-anxiety drug history; experiencing a Lumbar puncture and Bone Marrow Aspiration for at least once Exclusion criteria: having a history of ear surgery; having a history of relapses; unfinished patient's procedure for any reason; Doctor perform the procedure more than once acted; Need to receive pain killer and anti-anxiety during the procedure; Removing the headphones before the end of the procedure in the intervention group

#### Age

No age limit

#### Gender

Both

#### Phase

2

#### Groups that have been masked

No information

#### Sample size

Target sample size: 50

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

A randomized blocking method was used For randomization in this study

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tehran University of Social Welfare and Rehabilitation Sciences

##### Street address

KodakyarAve, daneshjou Blvd, Evin,Tehran

##### City

Tehran

##### Postal code

1985713834

#### Approval date

2016-01-12, 1394/10/22

#### Ethics committee reference number

IR.USWR.REC.1395.11

## Health conditions studied

### 1

#### Description of health condition studied

Anxiety

#### ICD-10 code

F41.1

#### ICD-10 code description

Generalized anxiety disorder

### 2

#### Description of health condition studied

Pain

#### ICD-10 code

R52

#### ICD-10 code description

Pain, not elsewhere classified

## Primary outcomes

### 1

#### Description

pain

#### Timepoint

30 minutes before the intervention, during the intervention, 30 minutes after the intervention

#### Method of measurement

Wong Baker faces scale, FLACC scale

### 2

#### Description

Anxiety

#### Timepoint

30 minutes before the intervention, 30 minutes after the intervention

#### Method of measurement

Revised Child Manifest Anxiety Scale(RCMAS)

## Secondary outcomes

### 1

#### Description

Respiratory Rate per Minute

#### Timepoint

30 minutes before intervention, during the intervention, 30 minutes after intervention

#### Method of measurement

Rate per minute

### 2

#### Description

Blood Oxygen Saturation level

#### Timepoint

30 minutes before intervention, during the intervention, 30 minutes after intervention

#### Method of measurement

Portable Pulse Oximeter

### 3

#### Description

Pulse Rate  
**Timepoint**  
30 minutes before intervention, during the intervention,  
30 minutes after intervention  
**Method of measurement**  
Portable Pulse Oximeter

#### 4

**Description**  
Systolic Blood pressure  
**Timepoint**  
30 minutes before intervention, during the intervention,  
30 minutes after intervention  
**Method of measurement**  
digital Manometer

#### 5

**Description**  
Diastolic Blood pressure  
**Timepoint**  
30 minutes before intervention, during the intervention,  
30 minutes after intervention  
**Method of measurement**  
digital Manometer

### Intervention groups

#### 1

**Description**  
Intervention group:30 minutes before and during the  
invasive procedure Participants in the intervention group  
listened to childish music through headphone  
**Category**  
Other

#### 2

**Description**  
Control group:Participants in control group received  
routine care and invasive Procedure was performed  
without special intervention  
**Category**  
Other

### Recruitment centers

#### 1

**Recruitment center**  
**Name of recruitment center**  
Dr.Mohammad Kermanshahi's Educational-Medical  
Hospital  
**Full name of responsible person**  
Nasrin Ghanbari  
**Street address**  
Dr.Mohammad Kermanshahi's Educational-Medical  
Hospital, Helal AhmarCross, Kermanshah  
**City**  
kermanshah

### Sponsors / Funding sources

#### 1

**Sponsor**  
**Name of organization / entity**  
Vice Chancellor for research of Tehran University of  
Social Welfare and Rehabilitation Sciences  
**Full name of responsible person**  
Nasrin Ghanbari  
**Street address**  
KodakyarAve, daneshjou Blvd, Evin,Tehran  
**City**  
Tehran  
**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 of Tehran University of  
Social Welfare and Rehabilitation Sciences  
**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**  
Tehran University of Social Welfare and Rehabilitation  
Sciences  
**Full name of responsible person**  
Hamid Reza khankeh  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**Web page address**

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## 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*