

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Study the Effect of Music on Anxiety, Pain and Hemodynamic Parameters in Burn Patients During Dressing

#### Protocol summary

##### Summary

1.Objectives: To assess the effects of music on anxiety, pain and hemodynamic parameters in patients with burns during dressing changes. 2. Design and how to do: This randomized clinical trial on 86 patients 2 and 3 bed burns in the burn Taleghani Hospital Ahwaz done in 1395. The samples were randomly assigned to two groups will be music and control so that each group contains 43 patients. 3.Participants including major eligibility criteria: desire to participate in the Study ability to read and write-ages of 18-60 years of addiction to drugs and alcohol Lack of mental illness-burn 10 to 45 percent with grade 2 and 3 - lack of burns to the head and face and ears .What having trouble hearing traverse at least 3 nights and exclusion criteria were discharged from the hospital during the study and wanting to continue to participate in the study. 4.Intervention: Patients for three consecutive days during a dressing change by entering the dressing room to run and to control their favorite music, usually performed dressing change. 5. main outcome: music reduced pain and anxiety as well as blood pressure and heart rate adjusted band in comparison with the control group of burn patients.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016100429733N2**  
Registration date: **2017-01-29, 1395/11/10**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-01-29, 1395/11/10

#### Registrant information

##### Name

Aliakbar Ataeikachouei

##### Name of organization / entity

Ahwaz Jundishapur University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3333 9995

##### Email address

ataeik-aa@ajums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Ahwaz Jundishapur University of Medical sciences

#### Expected recruitment start date

2016-12-21, 1395/10/01

#### Expected recruitment end date

2017-02-19, 1395/12/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Study the Effect of Music on Anxiety, Pain and Hemodynamic Parameters in Burn Patients During Dressing

#### Public title

The effect of music on burn pain

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Terms of Inclusion: Consent to Participate in Study; Ability to read and write; Age 18-60 years; Lack of addiction to drugs and alcohol; Lack of psychosexual disorders; Burn 10 to 45 percent with grade 2 & 3; No

burns the head and face and ears; Lack of hearing problem; stay minimum 3 night Terms of Exclusion: discharge during Study; The desire to withdraw from the study

#### Age

From **18 years** old to **60 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **86**

#### 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

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee Ahvaz Jundishapur University of Medical sciences

##### Street address

Ahvaz Jundishapur University of Medical sciences, Ahvaz, Golestan Blvd

##### City

Ahvaz

##### Postal code

#### Approval date

2016-08-13, 1395/05/23

#### Ethics committee reference number

IR.AJUMS.REC.1395.344

## Health conditions studied

### 1

#### Description of health condition studied

Burn

#### ICD-10 code

T21-T22-T2

#### ICD-10 code description

Burn and corrosion of trunk, Burn and corrosion of shoulder and upper limb, except wrist and hand, Burn and corrosion of wrist and hand, Burn and corrosion of hip and

lower limb, except ankle and foot, Burn and corrosion of ankle and foot

## Primary outcomes

### 1

#### Description

Blood Pressure

#### Timepoint

3 times in 3 days

#### Method of measurement

Mercury manometers

### 2

#### Description

Heart Rate

#### Timepoint

3 times in 3 days

#### Method of measurement

Manual

### 3

#### Description

pain

#### Timepoint

3 times in 3 days

#### Method of measurement

pain Chart

### 4

#### Description

Anxiety

#### Timepoint

3 times in 3 days

#### Method of measurement

Spielberger questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention: The intervention group will run for three consecutive days during a dressing change by entering the dressing room their favorite music

#### Category

Treatment - Other

### 2

#### Description

Control: control group performed for dressing as usual, no music and for three days

#### Category

Treatment - Other

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Burn Taleghani Hospital Ahvaz

**Full name of responsible person**

Fatemeh Jahangiri Mehr

**Street address**

Ayatollah Taleghani Hospital of Ahvaz, Khuzestan,  
Ahvaz, Amanollah Region, Mostaan Street

**City**

Ahvaz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Ahvaz Jundishapur  
University of Medical Sciences

**Full name of responsible person**

Behzad Sharif Makhmal Zadeh

**Street address**

Ahvaz Jundishapur University of Medical sciences,  
Ahvaz, Golestan Blvd

**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 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**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Fatemeh Jahangiri Mehr

**Position**

MSc in Biostatistics

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Ali Akbar Ataei

**Position**

SubSpecialist of Plastic and Reconstructive Surgeon

**Other areas of specialty/work**

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## Person responsible for updating data

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**Position**

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**Other areas of specialty/work**

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**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*