

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Comparison of the effect of auditory distraction and virtual reality distraction on pain, comfort, anxiety and physiological parameters during dressing change in burn patients

#### Protocol summary

##### Study aim

Determining and comparing the effect of two methods of auditory distraction and virtual reality distraction on pain, comfort, anxiety and physiological parameters during dressing change of burn patients

##### Design

The clinical trial with two intervention groups and one control group, with parallel groups, without blinding, using minimization or matched randomization method, on 60 patients, randomization will be done using minim software.

##### Settings and conduct

In the dressing room, the samples in the auditory distraction group will listen to no lyric music and the sounds of nature by headphone while dressing change, the samples in the virtual reality group will see images of the cosmos and nature while dressing change by using virtual reality headset. In the control group, the dressing will be changed as usual.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age 15 to 60 years, not having speech, vision, hearing and mental retardation, not having neurological defects such as (neuropathy of limbs, paralysis of limbs), burn level 5-50 percent, second and three-degree burns, 2-3 days of hospitalization and no pain before changing the dressing. Exclusion criteria: unwillingness to participate in the study, emergency conditions such as cardiopulmonary resuscitation or seizures, history of drug use, self-immolation patients who have psychiatric problems, and the presence of burns in the eye and ear areas.

##### Intervention groups

the auditory distraction group will listen to no lyric music and the sounds of nature by headphone while dressing change, and the virtual reality group will see images of the cosmos and nature by virtual reality headset while dressing change. Dressing in the control group will be

done as usual.

##### Main outcome variables

pain, comfort, anxiety and changes in physiological parameters

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220620055234N1**

Registration date: **2023-04-28, 1402/02/08**

Registration timing: **prospective**

Last update: **2023-04-28, 1402/02/08**

Update count: **0**

##### Registration date

2023-04-28, 1402/02/08

##### Registrant information

##### Name

Khatere Soori

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 991 049 1951

##### Email address

khatere.soori@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-06-04, 1402/03/14

##### Expected recruitment end date

2023-09-05, 1402/06/14

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of auditory distraction and virtual reality distraction on pain, comfort, anxiety and physiological parameters during dressing change in burn patients

**Public title**  
Examining auditory distraction and virtual reality distraction on pain, comfort, anxiety and physiological parameters of burn patients

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Age 15 to 60 years Not having speech, vision, hearing disorders Not having mental retardation Not having neurological defects such as (limb neuropathy, limb paralysis) Patient consent and willingness to cooperate The burn level is 5-50 percent in the body based on the doctor's diagnosis. Second and third degree burns based on doctor's diagnosis Hospitalization day 2-3 Not having pain before dressing change

**Exclusion criteria:**

Unwillingness to participate in the study Emergency conditions such as cardiopulmonary resuscitation or seizures History of drug abuse Self-immolation patients who have psychiatric problems Burns in the eyes and ears

**Age**  
From **15 years** old to **60 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients will be placed in two intervention groups and one control group by minimization method or matched randomization based on auxiliary variables. In this method, the first person will be randomly assigned to one of the groups, and the next people will be assigned to the group that has the least number of desired characteristics based on the degree of burn variable. This type of randomization method can be easily managed using minim software. The sequence of random allocation is done by the statistical consultant. Registration of people and their allocation to interventions will be done by the researcher.

**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 of Kermanshah University of Medical Sciences

**Street address**

Karmandan sreet of station 8, Shahid Rajaei sector, district 69, first floor, right side

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715975977

**Approval date**

2024-01-16, 1402/10/26

**Ethics committee reference number**

IR.KUMS.REC.1402.022

**Health conditions studied**

1

**Description of health condition studied**

Burn Patients

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

1

**Description**

Pain

**Timepoint**

5 minutes before dressing change - during dressing change - 5 minutes after dressing change

**Method of measurement**

Numeric rating scale

2

**Description**

Comfort

**Timepoint**

5 minutes after changing the dressing

**Method of measurement**

Visual Analogue Scale

### 3

**Description**

anxiety

**Timepoint**

5 minutes before changing the dressing - 5 minutes after changing the dressing

**Method of measurement**

Spielberger Situational Anxiety Questionnaire

### 4

**Description**

Changes in physiological indicators

**Timepoint**

5 minutes before dressing change - during dressing change - 5 minutes after dressing change

**Method of measurement**

Researcher's observations and pulse oximeter device

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

The first intervention group: the auditory distraction group, in which the samples will listen to a combination of no lyric music and the sounds of nature with headphone while changing the dressing until the end, immediately after taking a shower.

**Category**

Other

### 2

**Description**

The second intervention group: the virtual reality group, in which the samples will see images of the cosmos and nature during the dressing change until the end ,by using a virtual reality headset, immediately after taking a shower.

**Category**

Other

### 3

**Description**

Control group: Dressing will be changed as usual without any intervention.

**Category**

Other

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Golestan Accident and Burn Hospital, Kermanshah

**Full name of responsible person**

Khatere Soori

**Street address**

Sorkkeh Lije St., Nurse Blvd., Golestan Accident and Burn Hospital

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

75333-67427

**Phone**

+98 83 3727 6301

**Email**

irhk@kums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Syrus Jalili

**Street address**

Itsar Square, Daulat Abad Blvd., Faculty of Paramedicine.

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6714869914

**Phone**

+98 83 3827 9899

**Email**

sac\_paramedical@kums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Khatere Soori

**Position**

University student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Dovlat abad

**City**

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**Province**

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**Postal code**

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khatere.soori@kums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Khatere Soori

**Position**

University student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

University student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Phone**

+98 991 049 1951

**Fax****Email**

khatere.soori@kums.ac.ir

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

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

All data can be shared after de-identification.

**When the data will become available and for how long**

The access period starts 3 months after the results are published

**To whom data/document is available**

The data will be available only to researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

Analysis is allowed on the delivered data

**From where data/document is obtainable**

Through the researcher's email address :  
khatere.soori@kums.ac.ir

**What processes are involved for a request to access data/document**

First, the reason for requesting the data and introducing your resume and a full explanation about the possible use of the data should be emailed. Then the email will be answered within 1 month.

**Comments**