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
Sorkheh Lije St., Nurse Blvd., Golestan Accident and Burn Hospital
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75333-67427
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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.
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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
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Person responsible for updating data

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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