Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Music Therapy with Nature Sounds on Anxiety and Pain of Change Dressings For Burn Patients

Protocol summary

Study aim
Determining the effect of music therapy with the sounds of nature on anxiety and pain during dressing changes in burn patients

Design
Clinical trial with a control group, with parallel groups, single-blind, randomized on 86 burn patients Using the simple random method and using the table of random numbers

Settings and conduct
This research is an interventional study that will be conducted in Arak. After selecting the research samples, the patients will be divided into test and control groups randomly.Then, the patients of each group complete the demographic information,the pain intensity and Spielberger questionnaire.Then i before the start of the intervention, the level of pain and anxiety of the patient is measured while changing the patient's dressing, and on the second day of the intervention, the level of pain and anxiety of the patient is measured while changing the dressing.The intervention is carried out in such a way that the MP3 Player and headphones are used for two consecutive days during the dressing change. Start 15 minutes before changing the dressing and listen to the sounds of nature for 30 minutes respectively. they listen In addition, each one is presented for 5 minutes and this process is repeated for 30 minutes. Using the same method before the intervention and immediately after the intervention, the amount of basic pain and anxiety is measured.

Participants/Inclusion and exclusion criteria
Age from 18 to 65 years, patient's ability to answer the questions (in terms of physical and mental condition), written consent to participate in the study

Intervention groups
The intervention in this study includes playing music with the sounds of nature for 30 minutes while changing the patient's dressing.

Main outcome variables
Pain, anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170501033751N5**
Registration date: **2023-12-02, 1402/09/11**
Registration timing: **prospective**

Last update: **2023-12-02, 1402/09/11**
Update count: **0**

Registration date
2023-12-02, 1402/09/11

Registrant information

Name
rezvan ghafarzadegan

Name of organization / entity
Arak University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 86 3426 2226

Email address
rghafarzadegan@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-06, 1402/09/15

Expected recruitment end date
2024-03-05, 1402/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Music Therapy with Nature Sounds on Anxiety and Pain of Change Dressings For Burn Patients

Public title
The Effect of Music Therapy on Anxiety and Pain in Burn Patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 65 years, the patient's ability to answer questions (in terms of physical and mental condition), having a stable and stable hemodynamic status, 2nd or 2nd and 3rd degree burns together with a range of 15 to 60% who have passed the resuscitation or urgent stage, written consent to participate in the study
Exclusion criteria:
patient's neurological and mental disease addiction to cigarettes and other narcotic drugs Having comorbidity
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked

- Data analyser

Sample size
Target sample size: **86**
Randomization (investigator's opinion)
Randomized
Randomization description
After selecting the research samples, the patients will be divided into intervention and control groups using simple random method and random number table.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the person who analyzes the study data after entering the data into the statistical software is not aware of the allocation of the study groups and the type of intervention allocated and does not know which individual in the test group each of the data is related to. or control.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Khomein Faculty of Medical Sciences
Street address
No. 20, Building of the Vice-Chancellor of the Faculty of Medical SciencesKhomein,Quds Boulevard
City
Khomein
Province
Markazi
Postal code
3881857573
Approval date
2023-07-10, 1402/04/19
Ethics committee reference number
IR.KHOMEIN.REC.1402.002

Health conditions studied

1

Description of health condition studied
burn
ICD-10 code
M61.3
ICD-10 code description
Calcification and ossification of muscles associated with burns

Primary outcomes

1

Description
Pain score according to pain intensity questionnaire(primary outcome)
Timepoint
before the beginning of the stages and on the second day after the intervention
Method of measurement
Pain measurement questionnaire

2

Description
Anxiety score according to the Spielberger anxiety questionnaire(secondry outcome)
Timepoint
before the beginning of the stages and on the second day after the intervention
Method of measurement
Spielberger anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
"Intervention group:"Music therapy is performed using MP3 Player and headphones two days in a row at the time of dressing change, and they start 15 minutes before dressing change and listen to the sounds of nature for 30 minutes, which are birds singing, water and rain respectively. In addition, each type of music is presented for 5 minutes and this process is repeated for 30 minutes.

Category
Rehabilitation

2

Description
"Control group:" Dressing according to the doctor's order and in accordance with the usual treatment and without performing music therapy

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Amirulmomenin Arak Hospital

Full name of responsible person
rezvan ghafarzadegan

Street address
No. 20, Building of the Vice-Chancellor of the Faculty of Medical Sciences,Quds Boulevard

City
khomein

Province
Markazi

Postal code
3881743364

Phone
+98 86 4622 1534

Email
rghafarzadegan@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Khomein Faculty of Medical Sciences

Full name of responsible person
reza beiranvand

Street address
No. 20, Building of the Vice-Chancellor of the Faculty of Medical Sciences,Quds Boulevard

City
khomein

Province
Markazi

Postal code
3881743364

Phone
+98 86 4622 1534

Email
beiranvandreza@ymail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Khomein Faculty 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
Khomein Faculty of Medical Sciences

Full name of responsible person
rezvan ghafarzadegan

Position
academic instructor

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
No. 20, Building of the Vice-Chancellor of the Faculty of Medical Sciences,Quds Boulevard

City
khomein

Province
Markazi

Postal code
3881743364

Phone
+98 86 4622 1534

Email
rghafarzadegan@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Khomein Faculty of Medical Sciences

Full name of responsible person
reza beiranvand

Position
academic instructor

Latest degree
Master
Other areas of specialty/work
Epidemiology
Street address
No. 20, Building of the Vice-Chancellor of the Faculty of Medical Sciences,Quds Boulevard
City
khomein
Province
Markazi
Postal code
3881743364
Phone
+98 86 4622 1534
Email
beiranvandreza@ymail.com

Person responsible for updating data

Contact
Name of organization / entity
Khomein Faculty of Medical Sciences
Full name of responsible person
rezvan ghafarzadegan
Position
academic instructor
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
No. 20, Building of the Vice-Chancellor of the Faculty of Medical Sciences,Quds Boulevard
City
Khomein
Province
Markazi
Postal code
3881743364
Phone
+98 86 4622 1534
Email
rghafarzadegan@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data can be shared after de-identifying individuals
When the data will become available and for how long
1403
To whom data/document is available
All researchers
Under which criteria data/document could be used
To conduct related research
From where data/document is obtainable
No. 20, Building of the Vice-Chancellor of the Faculty of Medical Sciences,Quds Boulevard,Khomein, Mr. Reza Biranvand, phone number: 08646221534, fax: 08646224142
What processes are involved for a request to access data/document
Submitting a written request via fax to receive documents to the Vice-Chancellor of Education and Research of Khomein Faculty of Medical Sciences and receiving information related to the research after a maximum of one month.
Comments