Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the effect of Benson relaxation technique and the sound of nature on the pain anxiety and body image burn patients admitted to the intensive care unit.

Protocol summary

Study aim

The effect of Benson relaxation and nature sound on pain anxiety and body image in burn patients of intensive care unit of Zare hospital in Sari

Design

The clinical trial has a control group, a Benson relaxation group and a nature sound group. The process of simple random allocation will be done using software, random allocation. Sample blocking will be assigned to three groups of 60 people (20 people in each group).

Settings and conduct

The study is a randomized clinical trial. The research environment of the burn intensive care unit of Zare Hospital in Sari was considered. The intervention is performed for 7 consecutive days, in the morning, as well as measuring the mental image of the patients in week 3 and week 5.

Participants/Inclusion and exclusion criteria

Inclusion criteria: be alert and able to cooperate and communicate clearly with the researcher, having an age of 18 years and above, hospitalization in the burn ward that is 24 hours after the burn injury, having a second degree burn with an area of 30% and grade 3 burns. Exclusion criteria: aggravation of physical condition, death or discharge from the hospital during the study period, discoloration of the wound due to infection, inability to participate in the intervention for seven consecutive days, having a history of mental illness and patients with severe anxiety, mental-cognitive disability, drug addiction, blindness and deafness, failure to perform Relaxation skills after training during intervention and self-immolation

Intervention groups

In the group of nature sound, the sound of nature includes (the sound of birds, the quiet sound of rain, river flow, the sound of waterfalls and walking in the forest), all of which are recorded in a row. In the Benson relaxation group, the recorded audiotape instructs the patient to perform the Benson relaxation technique

Main outcome variables

Pain; anxiety and body image

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151004024342N8**
Registration date: **2021-09-06, 1400/06/15**
Registration timing: **prospective**

Last update: **2021-09-06, 1400/06/15**
Update count: **0**

Registration date

2021-09-06, 1400/06/15

Registrant information

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Vida Shafipour
Name of organization / entity
Mazandaran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of Benson relaxation technique and the sound of nature on the pain anxiety and body image burn patients admitted to the intensive care unit.

Public title
The effect of Benson relaxation technique and the sound of nature on the pain anxiety and body image burn patients admitted to the intensive care unit.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Be vigilant and able to cooperate and communicate clearly with the researcher Age 18 years old or older Hospitalized in a burn ward that is 24 hours after the burn injury Grade 2 burn with an area of 30% or more or a grade 2 burn with an area of 15% in case of involvement (head, neck and face, genital area) Grade 3 burns
Exclusion criteria:
Exacerbation of physical condition (connection to ventilator and decreased level of consciousness) Death or discharge from hospital during the study Discoloration of the wound due to infection (based on positive wound culture) Inability to participate in the intervention for seven days Consecutively History of mental illness (patients who, according to their statements and / or relatives and history in the file, history of psychiatric disorder and / or taking psychotropic drugs) Severe anxiety Mental-cognitive disability Drug addiction Blindness and deafness Lack of relaxation skills after training during the intervention Burns are due to self-immolation.
Age
From **18 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
In connection with the sampling method, first the samples with inclusion criteria will be selected by the available method, then using the method, the blocking of samples will be assigned to three groups. The process of simple random allocation will be done using software, random allocation. Group randomization is shown in Appendix 6. With random allocation software, 10 blocks of six will be produced.
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 Mazandaran University of Medical Sciences
Street address
Building No. 2, Vice Chancellor for Research, Mazandaran University of Medical Sciences, Moallem Square
City
Sari
Province
Mazandaran
Postal code
4816715793
Approval date
2021-08-28, 1400/06/06
Ethics committee reference number
IR.MAZUMS.REC.1400.379

Health conditions studied

1

Description of health condition studied
Burn patients
ICD-10 code
T20 - T25
ICD-10 code description
burns and corrosions of: first degree [erythema] second degree [blisters] [epidermal loss] third degree [deep necrosis of underlying tissue] [full-thickness skin loss]

Primary outcomes

1

Description
Pain anxiety
Timepoint
Pain Anxiety Questionnaire (before the intervention and before changing the dressing (first time = T1), after the intervention and before changing the dressing and before taking painkillers (second time = T2) and after changing the dressing (Third time = T3)) is evaluated on the first, fourth and seventh days.

Method of measurement
Burn Specific Pain Anxiety Scale (BSPAS)

2

Description
Body image
Timepoint
Body image of the body in patients with burns is performed the day before the intervention and 7 days after the intervention. Also, the assessment of the body image of the patients' bodies is continued and performed in week 3 and week 5. The intervention is performed in the first week with the presence of the researcher. After that, the intervention of the trainings given to the patients by the researcher, the intervention is performed by the patients themselves every day at a certain time of the day and regularly and the interventions are followed by the researcher.
Method of measurement
Satisfaction With Appearance Scale (SWAP)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In the group of nature sound for patients, the sound of nature includes (bird sound, calm rain sound, river flow, waterfall sound and walking in the forest) where all sounds are recorded in a row and through metronome software and After consulting with an expert musician, it is approved and used by the speaker for 30 minutes in the morning before changing the dressing and before taking painkillers for patients, and the volume of the speaker based on patients' requests and on average in the range Is set at 25 to 50 dB and patients are asked to close their eyes and relax while listening to the sounds of nature, including unpleasant thoughts (body image problems that cause symptoms such as Grief, sadness, distance from people, extreme sensitivity, impaired self-perception, and lack of self-confidence can be avoided.
Category
Treatment - Other

2

Description
Intervention Group II: In the Benson Relaxation Group recorded audio tape Instructions for performing the Benson Relaxation technique using a speaker For the patient in the morning (30 minutes before changing the dressing and before taking painkillers) is spread in the patient's room and taught by the researcher.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Zare Hospital
Full name of responsible person
Hadis Javadian Kutenai
Street address
Sari Zare Psychiatric and Burn Hospital - km 3 of Sari Neka road
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4843185774
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Ahmad Ali Enayati
Street address
Vice Chancellor for Research, Mazandaran University of Medical Sciences, Moallem Street, Moallem Square
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4815696869
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hjkp7595@mail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Vida Shafipour

Position
PhD in Educational Nursing-faculty member

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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