

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Favorite music effect on sleep quality and the underlying pain of burn patients

Protocol summary

Summary

This study is a clinical trial. The aim of this study was to compare the effect of music on sleep quality and pain in burn patients is preferred. The number of samples are 50 burned patients that will hospitalize in burn ward in Shahid Motahari Burn Hospital in Tehran. The process of sampling will do during five month using the method of purposive sampling and the samples will place in two groups (25 patients) using the software of random allocation. Inclusion criteria: Willingness to participate in the study; Ability to read and write; the patients that have sleep disorders; Age between 18 to 60 years old; Not drug and alcohol addicted; Not taking sleeping pills or anti-anxiety drugs; Having no mental disorders :depth of burn:2,3 grade; total burn surface area: %10 - %45; Having no burn the scalp, face and ears; Having no hearing impairment; Spend at least 3 nights of hospitalization; Understanding Persian language; Having no history of burns. Exclusion criteria: Discharge; Willingness to quit from the study. after knowing that the patients have inclusion criteria, the researcher will give them clear and understandable information about the method of study and then catch them a testimonial. In two groups, in the first three nights hospitalized in burn ward, researcher will not do no intervention on patients and only, patients fill the Pittsburgh sleep quality questionnaire and horizontal measurement tool for pain (VAS) on the next day, before sleeping. then in forth night for 3 nights (45 minutes), the patients in the intervention group will listen to their favorite and light music by choosing it from a list by a MP3player that has a headphone and then fill the questionnaires on the next day, before sleeping. In addition, patients in both groups, use sedative and sleeping drugs if they needed if they needed. Finally, the mean score of sleep quality and pain in two groups analyze before and after the intervention .

General information

Acronym

Not

IRCT registration information

IRCT registration number: **IRCT2015111525054N1**

Registration date: **2016-02-20, 1394/12/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-20, 1394/12/01

Registrant information

Name

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Name of organization / entity

Iran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2015-10-02, 1394/07/10

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Favorite music effect on sleep quality and the underlying pain of burn patients

Public title

The effects of music on sleep quality and pain in burn patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Willingness to participate in the study; Ability to read and write; the patients that have sleep disorders; Age between 18 to 60 years old; Not drug and alcohol addicted; Not taking sleeping pills or anti-anxiety drugs; Having no mental disorders :depth of burn:2,3 grade; total burn surface area: %10 - %45; Having no burn the scalp, face and ears; Having no hearing impairment; Spend at least 3 nights of hospitalization; Understanding Persian language; Having no history of burns. Exclusion criteria: Discharge; Willingness to quit from the study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Not

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Highway Hemmat, Tehran

City

Tehran

Postal code

Approval date

2015-08-05, 1394/05/14

Ethics committee reference number

IR.IUMS.REC.1394.9211196226

Health conditions studied

1

Description of health condition studied

Burn

ICD-10 code

T30.0

ICD-10 code description

Burn of unspecified body region, unspecified degree burn

Primary outcomes

1

Description

Pain

Timepoint

6 nights in a row

Method of measurement

Horizontal analogue scale VAS

2

Description

Quality of Sleep

Timepoint

6 nights in a row

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description

In the experimental group, the second night of hospitalization, For 3 nights patients received no intervention and The day after the night before, Pittsburgh Sleep Quality Index and horizontal tool will complete pain assessment The average score of 3 nights will be achieved: Then the night quarter of the patients for 3 nights in music for 45 minutes using a player with headphones fall and The morning after patients have completed the questionnaires And the average score will be 3 nights before the intervention(Patients gentle instrumental music and your favorite music list has been prepared by the researcher selected).

Category

Treatment - Drugs

2

Description

The control group as well as groups, Pittsburgh Sleep Quality Index and Horizontal tool to measure pain will be completed in 6 consecutive nights, The difference is that the control group receiving only routine care And any intervention will be done for them and The only assess the quality of sleep and pain in proportion to the period, similar tests shall take place.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Martyr Motahari Burn Center in Tehran

Full name of responsible person

Samira Abdi Nursing Graduate Student

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Motahari Burn Center in Tehran

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Iran University of Medical Sciences

Street address

Hemmat, Iran University of Medical Sciences, Tehran, Iran

City

Tehran

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source**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

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

Iran University of Medical Sciences

Full name of responsible person

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Street address

Hemmat, Iran University of Medical Sciences, Tehran, Iran

City

Tehran

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

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Iran University of Medical Sciences

Proportion provided by this source**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**

Iran University of Medical Sciences

Full name of responsible person

Samira Abdi Nursing Graduate Student

Position

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Contact

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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