

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Effects of nature's sound on pain and anxiety in patients with fractures of the leg in the emergency department

Protocol summary

2018-09-10, 1397/06/19

Study aim

Determination of the effect of nature's sound on pain and anxiety of patients with fracture of the leg in the emergency department

Design

The intervention consists of collection of the Voice of Nature album, which is listened to by an audio player and headphone for 15 minutes. For the control group, headphones without music playback for 15 minutes along with routine care is used.

Settings and conduct

This study was done in Emam Khomeini hospital of Sary affiliated to Mazandaran University of Medical sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria includes: age from 20 to 60 years, full consciousness, ability to read and write, lack of hearing and right-handedness, and exclusion criteria includes: receiving sedatives and analgesics before entering the study, taking anti-anxiety drugs and zero pain in Initial assessment.

Intervention groups

Each of the intervention and control groups includes 32 subject.

Main outcome variables

Pain, Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140721018550N6**

Registration date: **2018-09-10, 1397/06/19**

Registration timing: **prospective**

Last update: **2018-09-10, 1397/06/19**

Update count: **0**

Registration date

Registrant information

Name

Nayyereh Raiesdana

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 3867

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nr_dana@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of nature's sound on pain and anxiety in patients with fractures of the leg in the emergency department

Public title

Effects of nature's sound on pain and anxiety of patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 20-60 years Full consciousness Ability of reading and writing No hearing problems Right-handed

Exclusion criteria:

Taking a sedative medication before the study
Taking a narcotic analgesic before the study
Use of anti-anxiety drugs
Zero pain in the initial assessment

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

We first assign four subgroups (stratum): 1 - Women 20 to 40 years 2 - Men 20 to 40 years 3 - Women over 40 to 60 years 4 - Men over 40 to 60 years old Each patient enrolled in the study is placed in one of these four groups. Then, using the randomized random list for each stratum (4 predefined lists), that person is in the intervention group A or control B. To create the desired list of 6 possible blocks, we assign quadrants to each numerical block (from I to VI): According to the random numbers table, numbers 1 through 6 correspond to the above blocks and do not count numbers 7 to 9 and 0. Random numbers are generated with Excel. Then the assignment list (from left to right) is determined for each stratum.

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 Semnan University of Medical Sciences

Street address

Nursing and Midwifery college, Semnan University of Medical Sciences, Kilometer5 Damghan road, Semnan, Iran

City

Semnan

Province

Semnan

Postal code

3513138111

Approval date

2018-08-21, 1397/05/30

Ethics committee reference number

IR.SEMUMS.REC.1397.120

Health conditions studied

1

Description of health condition studied

Leg fracture

ICD-10 code

S82.2

ICD-10 code description

Fracture of shaft of tibia with or without mention of fracture of fibula

Primary outcomes

1

Description

Pain

Timepoint

Immediately before the intervention and fifteen minutes after the first time

Method of measurement

Numerical Rating Score (NRS) for pain

2

Description

Anxiety

Timepoint

Immediately before the intervention and fifteen minutes after the first time

Method of measurement

6- item Spillberger inventory for State anxiety

Secondary outcomes

1

Description

Systolic and Diastolic Blood Pressure

Timepoint

Immediately before the intervention and fifteen minutes after the first time

Method of measurement

Sphygmomanometer

2

Description

Heart Rate

Timepoint

Immediately before the intervention and fifteen minutes after the first time

Method of measurement

Portable Monitor

3

Description

Oxygen Saturation

Timepoint

Immediately before the intervention and fifteen minutes after the first time

Method of measurement

Pulse oximeter

Intervention groups

1

Description

Intervention group: Music without words is the nature's sound, which is a collection of the nature's sound album (the sound of rain falling, the sound of the waves of the sea and the river, the sound of water, the sound of birds and the sound of the forest), prepared by Dr Arend Stein (2011) that will be heard in the range of 25-30 dB, using a sound player and headphone for 15 minutes.

Category

N/A

2

Description

Control group: For the control group, headphones without music playback are used for 15 minutes in addition to routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Sari

Full name of responsible person

Dr.Misagh Shafieezadeh

Street address

Razi St., Imam Khomeini Hospital, Sari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr Parviz Kokhaei

Street address

Vice chancellor for research and technology, Semnan University of Medical Sciences, Basij Boulevard, Semnan, Iran

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3514799442

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kokhaei@semums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Nayyereh Raiesdana

Position

PhD. Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is not a plan to make this available.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

there is no more information.

When the data will become available and for how long

After termination of the study

To whom data/document is available

1-Faculty members2-The clinical nurses3- The medical,
Nursing and Emergency students

Under which criteria data/document could be used

1- For citation to this study2- For use to future study

From where data/document is obtainable

Please contact with Nayyereh Raiesdana at
nr_dana@yahoo.com

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

After emailing to Nayyereh Raiesdana, email will be
answered as soon as possible.

Comments