Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

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
2018-09-10, 1397/06/19

Registrant information
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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 colledge, 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 Shafiezadeh
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr Parviz Kokhaei
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Vice chancellor for research and technology, Semnan University of Medical Sciences,.Basij Bolevard, Semnan, Iran
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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
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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