Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of music therapy on pain and anxiety of patients undergoing wound healing with suturing techniques in emergency departments

Protocol summary

Study aim

Determining the effect of music therapy on pain and anxiety of patients undergoing wound healing with suturing techniques in emergency departments

Design

The present study is a parallel randomized controlled clinical trial.Eligible patients are divided into two groups of 30 intervention and control.

Settings and conduct

In the present study, there is a type of music without traditional Iranian words to be played for patients.In the intervention group, music will be played from the time the patient is in bed until the end of the stitches and no music will be played in the control group.The study place is the emergency department of Imam Khomeini and Bu Ali Sina hospitals in Sari.

Participants/Inclusion and exclusion criteria

In clusion criteria:Rupture of 5 cm or less in limbs that require sutures,Being 18-65 years old . Exclusion criteria:The patient does not cooperate during the process for any reason,The researcher will not be able to intervene during the procedure according to the patient's condition,Mental, auditory, speech, physical and motor disabilities and paralysis of the limbs,Receiving anti-anxiety medications,Take painkillers for 12 hours before the study,Having tears that involve the tendons and ligaments,Severe psychiatric disorders and medication,Getting Cancer,Rheumatic disease and drug treatment,Existence of rupture due to self-mutilation,Existence of multiple tears and simultaneous damage to other organs,Opioid addiction.

Intervention groups

Intervention group: playing music with headphones by the researcher starts from the time the patient is on the bed for stitches and continues until the end of the stitches. Control group: In this group, patients are stitched according to normal routine and music is not played for them

Main outcome variables

The amount of pain and anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110906007494N42**
Registration date: **2021-11-10, 1400/08/19**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-10, 1400/08/19**
Update count: **0**

Registration date

2021-11-10, 1400/08/19

Registrant information

Name

Masoumeh Bagheri Nesami

Name of organization / entity

Mazandaran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-10, 1400/08/19

Expected recruitment end date

2022-11-10, 1401/08/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of music therapy on pain and anxiety of patients undergoing wound healing with suturing techniques in emergency departments

Public title
The effect of music therapy on pain and anxiety

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Satisfaction with participation in the study. Rupture 5 cm or less in limbs that require sutures. Being 18-65 years old.

Exclusion criteria:
The patient does not cooperate during the process for any reason. The researcher will not be able to intervene during the procedure according to the patient's condition. Mental, auditory, speech, physical and motor disabilities and paralysis of the limbs. Receiving anti-anxiety medications. Take painkillers for 12 hours before the study. Having tears that involve the tendons and ligaments. Severe psychiatric disorders and medication. Getting Cancer. Rheumatic disease and drug treatment. Existence of rupture due to self-mutilation. Existence of multiple tears and simultaneous damage to other organs. Opioid addiction.

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: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Blocking method will be used for random allocation of samples. For this purpose, quadruple blocks will be considered. The six possible blocks are TTCC, TCTC, TCCT, CCTT, CTCT, CTTC, where T is for the intervention group and C is for the control group. The numbers will be generated randomly (with the RANDBETWEEN command in Excel software and in the range 1 to 6) and selected according to the production values of one of the blocks (for the production number 1 CTTC block, for the production number 2 CTCT blocks and so on) and sample Will be allocated.

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
Mazandaran University of Medical Sciences, Vice chancellor for research, Moalem street,Moalem square

City
sari

Province
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Postal code
4816715793

Approval date
2021-10-12, 1400/07/20

Ethics committee reference number
IR.MAZUMS.REC.1400.480

2

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Name of ethics committee
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Mazandaran

Postal code
4816715793

Approval date
2021-10-12, 1400/07/20

Ethics committee reference number
IR.MAZUMS.REC.1400.480

Health conditions studied

1

Description of health condition studied
Wound healing

ICD-10 code
Y74.3

ICD-10 code description
Surgical instruments, materials and general hospital and personal-use devices (including sutures) associated with adverse incidents

Primary outcomes

1

Description
pain
Timepoint
For the intervention and control groups once after bed rest and the second time after washing and anesthesia injection
Method of measurement
Visual Analogue Scale

2

Description
Anxiety disorders
Timepoint
For the intervention and control groups once after bed rest, the second after washing and injecting anesthesia, and the third after suturing
Method of measurement
facial anxiety scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Traditional Iranian non-verbal music is played from the time the patient is placed on the bed, for washing and stitching until the end.Pain is measured by Visual Analogue Scale. Pain is measured in two stages before the intervention and after anesthesia injection Taken. Anxiety is measured with Faces Anxiety Scale in three stages before the intervention, after anesthesia injection, and after suturing.Traditional Iranian non-verbal music, a piece of the morning courier composed by Homayoun Khoram and played by Babak Shahraki, is played to the patient with the help of headphones. The method of performing this song is three playing with dulcimer, violin and tombak and its duration is 1 minute and 54 seconds. This song is recorded for 20 minutes in a row so that there is no gap in its playing during wound healing and until the end of healing. to be continued. Its sedation was determined by MT30 at a rate of 76 beats. Due to the fact that the beat is between 60 and 80, this music is soothing, the song will be recorded on a memory card and played with SONY brand headphones.
Category
Treatment - Devices

2

Description
Control group: In the control group, patients will be stitched as usual and no music will be played for them and for them, music will not be played and the pain will be measured in the same two stages, ie after the patient is placed on the bed and after the wound is washed and the anesthetic is injected. Anxiety will be measured in three stages, first after the patient is placed on the bed, second after washing and anesthesia injection, and third after suturing.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini hospital
Full name of responsible person
Javad Hedayati
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Mazandaran University of Medical Sciences, Vice chancellor for research, Moalem street, Moalem square, Sari, Mazandaran, Iran
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Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person

Dr Majid saeedi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Mazandaran Mideacal Science

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
Dr.Masoumeh Bagheri Nesami

Position
PhD in Nursing Education

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Nursery

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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
En There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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