

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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

Inclusion 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

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sari

Province

Mazandaran

Postal code

4816715793

Approval date

2021-10-12, 1400/07/20

Ethics committee reference number

IR.MAZUMS.REC.1400.480

2**Ethics committee****Name of ethics committee**

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Postal code

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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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Recruitment center

Name of recruitment center

Bu Ali Sina Hospital

Full name of responsible person

Javad Hedayati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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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 scientific
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Person responsible for updating data

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Latest degree

Ph.D.

Other areas of specialty/work

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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