Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of music therapy on the pain of 3- to 6-year-old children undergoing suture wound healing and their parents' anxiety in the emergency department.

Protocol summary

Study aim
Determining the effect of music therapy on the pain of children aged 3 to 6 years under wound healing by stitching and their parents' anxiety in the emergency department.

Design
The present study is a random clinical trial of parallel witnesses, with qualified patients divided into two groups of 60 intervention and control.

Settings and conduct
In the present study, Iranian childish music is played in the outpatient operating room with respect to the age of children 3 to 6 years. . Children's pain and parental anxiety with the scales of pain on the face of Wong Baker and the short -sighted Spyberger positioning questionnaire are measured before the wound washing, and immediately after lidocaine injection. Finally, at the end of the suture and before the patient discharged, the amount of child's pain and anxiety is measured and the music is cut off. The study site is the emergency department of Valiasr Hospital in Ghaemshahr.

Participants/Inclusion and exclusion criteria
Entry Criterion: Rupture in the face area less than 3 cm requires suture. Having age 6-3 years, Mental disability, vision, hearing, speech, physical -motor and palsy. Pain analgesics and the child has not taken painkillers before suture. Parents are next to the child. Not having a child with neuromacular diseases. Lack of sensory disorders in the child. No need for sutures around the eyes. Simultaneously to other organs. Lack of child parenting with neurological and mental illnesses.

Intervention groups
Intervention Group: The music player broadcasts with a mobile phone from the time of the child in the outpatient operating room until the end of the procedure and clearance. Control Group: Children will be sutured as usual and music will not be played for them.

Main outcome variables
The emount of pain and anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110906007494N43**
Registration date: **2022-10-24, 1401/08/02**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-24, 1401/08/02**
Update count: **0**

Registration date
2022-10-24, 1401/08/02

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-23, 1401/08/01

Expected recruitment end date
2023-05-21, 1402/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of music therapy on the pain of 3- to 6-year-old children undergoing suture wound healing and their parents' anxiety in the emergency department.

Public title
The effect of music therapy on the pain of children and their parents' anxiety
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Consent to participate in the study. A tear of 3 cm or less in the face that requires sutures. Having an age of 3 to 6 years. Presence of parents with the child
Exclusion criteria:
The child and the family do not cooperate for any reason while interfering. The researcher is not able to intervene during the child's status according to the condition of the child, that is, if the child is restless and the parents become stressed and symptoms of agitated for the child's music during the study. Mental disability, vision, hearing, speech, physical -motor and organ paralysis. Ruptures that need sedation. Baby with neurological and mental illnesses treated. Baby with diabetes. Ruptures that need analgesic and the baby has not taken painkillers before suture. Child with neuromacular disease. Sensory disorders in children. Parents of the child with psychiatric diseases treated. No need to suture around the eye. Absence of multiple ruptures and simultaneous damage to other organs.
Age
From **3 years** old to **6 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
The blocking method will be used to randomly allocate samples which is the tool for generating block random sequence, random allocation software 2. It should be noted that in the random assignment process only subgroup will be considered and the age of children only includes the age range of 3 to 6 years. Depending on the sample size, 30 four blocks will be considered, which are inside each block 2 girls and 2 boys, and one girl and one boy will be in each test and control groups. Children will also be matched by parents (parents). For this purpose, there are 20 blocks for the mobile mother (80 mothers and children in each group 40 mothers and children) and 10 blocks for mobile fathers (40 fathers and children in each group of 20 parents) will be. The envelopes are hidden so that the cards are designed in the form of a block classification from 1 to 120 and are placed inside the envelope. The envelopes are not transparent and their doors are sealed, so random hiding is done.
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
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Approval date
2022-10-08, 1401/07/16
Ethics committee reference number
IR.MAZUMS.REC.1401.340

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
The pain measurement of children in the intervention

and control groups is done before washing the wound, immediately after the injection of lidocaine and the end of the suture.

Method of measurement

Pain scale from Wong Baker's face

Secondary outcomes

1

Description

anxiety

Timepoint

Parental anxiety control is done before washing the wound and after finishing the suture in children of the intervention and control groups.

Method of measurement

Shortened Spielberger situational anxiety questionnaire.

Intervention groups

1

Description

Intervention group: In the intervention group, immediately after the presence of the children in the ambulatory operating room, Iranian children's wordless music called Badbadek, composed by Mr. Amir Hossein Sargazi, is played in the ambulatory operating room. to be The performance of this song is multi-instrumental and includes guitar, bass, drums, string group (violins) and bells, and its duration is 3 minutes and 19 seconds. This song is recorded continuously for 15 minutes until there is a gap in the playback. It does not happen during wound healing and continues until the end of healing. Its sedation was determined by the MT30 device at the rate of 78 beats. Considering that the beat is between 60 and 80, this music is soothing and is played using a Xiaomi mobile phone in the ambulatory operating room at a distance of one meter from the child's head. Children's pain and parents' anxiety are measured with Wongbaker's facial pain scale and Spielberger's shortened situational anxiety questionnaire before washing the wound, immediately after lidocaine injection, children's pain is measured. Finally, at the end of the suture and before the patient's discharge, the amount of children's pain and parents' anxiety is measured and the music is stopped.

Category

Treatment - Devices

2

Description

Control group: In the control group, the children were stitched according to the usual routine and no music was played for them, after placing the patient on the bed and before washing the wound, the children's pain level and the parents' anxiety were measured, immediately after lidocaine injection, the children's pain level in The control group is measured. Finally, after the suture is finished, the amount of children's pain and parents' anxiety is measured.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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

Mazandaran 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

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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
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