Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect two methods of rhythmic breathing and music therapy on pain intensity, anxiety and hemodynamic indicators of patients after orthopedic surgery

Protocol summary

Study aim
Determination and comparison of pain intensity, anxiety level and hemodynamic indicators (pulse rate and blood pressure) between three groups (rhythmic breathing, music therapy, control) in the first 24 hours (end of the first 12 hours and the second 12 hours) after orthopedic surgery.

Design
This research is a single-blind controlled clinical trial study that will be conducted on patients who undergo lower limb orthopedic surgery or internal fixator in the male and female orthopedic departments of Shahid Chamran Hospital in Shiraz in 1402.

Settings and conduct
The environment of this research is the male and female orthopedic departments of Shahid Chamran Hospital in Shiraz.

Participants/Inclusion and exclusion criteria
Inclusion :Consent to participate in the research - have minimum reading and writing literacy - not suffering from mental disorders based on medical records... Exclusion: - Refusal to participate in the research - Need for re-surgery during the study Getting other diseases while doing research...

Intervention groups
For the first group (rhythmic breathing), before the operation (when the patient's condition is necessary), the researcher will teach how to perform rhythmic breathing. Berger) they will also be controlled at the same time with pain intensity and will be compared with other groups. For the second group (music therapy) there are also wordless and arbitrary musics (from among the four wordless musics of Baran Eshgh by Nasser Chashm Azar and three works by Dr. Arendstein called Peace in Dreams and two motivational pieces) for each of patients will be used and before the operation these musics will be played for each patient and their desired music will be selected.

Main outcome variables
intensity of pain ; The level of anxiety ; Pulse count ; blood pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231024059844N1**
Registration date: **2023-11-23, 1402/09/02**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-23, 1402/09/02**
Update count: **0**

Registration date
2023-11-23, 1402/09/02

Registrant information

Name
Mitra Zarei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3620 3184

Email address
mytrazary754@zbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-06, 1402/08/15

Expected recruitment end date
2024-07-05, 1403/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect two methods of rhythmic breathing and music therapy on pain intensity, anxiety and hemodynamic indicators of patients after orthopedic surgery

Public title

Comparison of the effect two methods of rhythmic breathing and music therapy on pain intensity, anxiety and hemodynamic indicators of patients after orthopedic surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Consent to participate in the research Having at least reading and writing literacy Not suffering from mental disorders based on medical records No history of taking psychiatric drugs and anti-anxiety drugs in the last 6 months Age 30 to 70 years Performing orthopedic surgery on the lower limb or placing an internal fixator No previous history of fracture and orthopedic surgery A fracture in a lower limb or the need for a fixator in a limb No trauma to the head, chest and abdomen No hearing disorders Hospitalization after surgery No respiratory disease (asthma, bronchitis, etc.) No diabetes No drug addiction Analgesic injection more than 4 hours before measuring the desired variables

Exclusion criteria:

Withdrawal from participating in the research Need for re-surgery during the study Getting other diseases while doing research The use of local drugs or other measures (hypnosis, distraction, etc.) that can affect pain, anxiety, or hemodynamic indicators during the study. Analgesic injection less than 4 hours before measuring the desired variables

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, research samples will be selected from among the patients who refer to Shahid Chamran Hospital in Shiraz for orthopedic surgery and meet the criteria for entering the research, and will be randomly assigned (so that the first sample of the research In the first intervention group (rhythmic breathing), the next sample in the second intervention group (music therapy) and the next sample in the control group) patients will be placed in three groups until the sample size is completed.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study will be conducted as a one-sided blind controlled clinical trial (one-sided blind: the meaning is that the subjects do not know which of the groups they are in).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zabul University of Medical Sciences

Street address

Sistan and Baluchestan province, Zabul city - 11 Ferdowsi St., next to the registry office

City

zabol

Province

Sistan-va-Balouchestan

Postal code

9861734184

Approval date

2023-10-11, 1402/07/19

Ethics committee reference number

IR.ZBMU.REC.1402.082

Health conditions studied

1

Description of health condition studied

Orthopedic surgery

ICD-10 code

Z47.82

ICD-10 code description

Encounter for orthopedic aftercare following scoliosis surgery

Primary outcomes

1

Description

intensity of pain

Timepoint

The first 12 hours and the second 12 hours after surgery

Method of measurement

Pain Visual Scale Questionnaire

2

Description

The level of anxiety

Timepoint

The first 12 hours and the second 12 hours after surgery

Method of measurement

Spielberger questionnaire

3

Description

Pulse count

Timepoint

The first 12 hours and the second 12 hours after surgery

Method of measurement

Pulse count in one minute

4

Description

blood pressure

Timepoint

The first 12 hours and the second 12 hours after surgery

Method of measurement

Measurement by pressure gauge

Secondary outcomes

1

Description

intensity of pain

Timepoint

The first 12 hours and the second 12 hours after surgery

Method of measurement

Visual analog scale questionnaire

2

Description

The level of anxiety

Timepoint

The first 12 hours and the second 12 hours after surgery

Method of measurement

Spielberger questionnaire

3

Description

Pulse count

Timepoint

The first 12 hours and the second 12 hours after surgery

Method of measurement

Pulse count in one minute

4

Description

blood pressure

Timepoint

The first 12 hours and the second 12 hours after surgery

Method of measurement

Measurement by pressure gauge

Intervention groups

1

Description

Intervention group:For the first group (rhythmic breathing), before the operation (when the patient's condition is necessary), the researcher will teach how to perform rhythmic breathing in such a way that the patients are able to do this. After the patient regains consciousness and it is confirmed by the anesthesiologist, during the first 24 hours, i.e. at the end of the first 12 hours and at the end of the second 12 hours after the patient regains consciousness, rhythmic breathing by the patient for 20 minutes while In each stage, they count from 1 to 3 and while breathing, they only focus on the inflow and outflow of air, once every five minutes, one minute each time, and immediately after each stage, the intensity of pain is controlled using a visual pain control scale. will be. In addition, their pulse rate, blood pressure and anxiety (Spielberger questionnaire) will be controlled at the same time as pain intensity and will be compared with other groups.

Category

Treatment - Other

2

Description

Intervention group: For the second group (music therapy) there are also wordless and arbitrary musics (from among the four wordless musics of Baran Eshgh by Nasser Chashm Azar and three works by Dr. Arendstein called Peace in Dreams and two motivational pieces) for each of patients will be used and before the operation these musics will be played for each patient and their desired music will be selected. In this group, after the patient regains consciousness and is confirmed by the anesthesiologist, during the first 24 hours, i.e. at the end of the first 12 hours and at the end of the second 12 hours after the patient regains consciousness, the music they want is played through The music player (headphones) will be played for 20 minutes for each patient and immediately after each stage, pain intensity (visual pain scale), pulse rate, blood pressure and anxiety (Spielberger questionnaire) will be controlled in each of the research samples. It will be compared with other groups

Category

Treatment - Other

3

Description

Control group: It will include patients for whom no intervention will be performed and they will only be

under the usual care of the hospital, and at the end of the first 12 hours and the second 12 hours after surgery, their pain intensity, anxiety level and hemodynamic indicators will be controlled. and will be compared with other groups. It should be noted that in all three groups, in case of need for housing or any other care, the required medical care will be performed according to the routine and none of these cares will be omitted.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Chamran Hospital, Shiraz
Full name of responsible person
Dr. Seyed Ali Hashemi
Street address
Shiraz Shahid Chamran Blvd
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+98 71 3623 4507
Email
chamhosp@sums.ac.ir
Web page address
https://chamran.sums.ac.ir/riasat

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zabol University of Medical Sciences
Full name of responsible person
Dr. Khadijah Rezaei Kikhaei
Street address
Zabol, Jihad Square, Shahid Bagheri St., Zabol University of Medical Sciences Headquarters
City
Zabol
Province
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9861663335
Phone
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Email
info@zbmu.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zabol University of Medical Sciences
Proportion provided by this source
20
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
Zabol University of Medical Sciences
Full name of responsible person
Mitra Zarei
Position
Master's student in internal surgical nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Shiraz - Golestan town - Baharestan street - 13 alley - left side - first building - third floor - unit 6
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Person responsible for scientific inquiries

Contact

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Dr. Hossein Shahdadi
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University faculty member
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Ph.D.
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Person responsible for updating data

Contact
Name of organization / entity
Zabol University of Medical Sciences
Full name of responsible person
Mitra Zarei
Position
Master's student in internal surgery
Latest degree
Bachelor
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Nursery
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Shiraz - Golestan town - Baharestan street - 13 alley - left side - first building - third floor - unit 6
City
Shiraz

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 are no plans to release it
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