

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 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@zsbmu.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 Zabol University of Medical Sciences

Street address

Sistan and Baluchestan province, Zabol 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

City

Shiraz

Province

Fars

Postal code

7194815644

Phone

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Fax

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Email

chamhosp@sums.ac.ir

Web page address

<https://chamran.sums.ac.ir/riasad>

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

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Sistan-va-Balouchestan

Postal code

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

City

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Province

Fars

Postal code

7189838786

Phone

+98 71 3620 3184

Email

mytrazary754@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zabol University of Medical Sciences

Full name of responsible person

Dr. Hossein Shahdadi

Position

University faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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mytrazary754@gmail.com

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

Other areas of specialty/work

Nursery

Street addressShiraz - 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