

# 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**

+98 71 3623 4507

**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

**Province**

Sistan-va-Balouchestan

**Postal code**

9861663335

**Phone**

+98 54 3222 5402

**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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**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

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Sistan and Baluchestan province, Zabol city - 11  
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7189838786

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**Email**

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 address**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