

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of progressive muscle relaxation technique on pain and anxiety of patients undergoing orthopedic surgery

Protocol summary

Study aim

Investigating the Effect of Progressive Muscle Relaxation in Patients with Broncho Anxiety Patients Candidate of Orthopedic Surgery

Design

Clinical trials with control group, blind, randomized. A sample of 80 patients with lower limb fractures are candidates for orthopedic surgery that are admitted to the orthopedic unit of Khatam Al Anbia Hospital. After obtaining written consent, samples will be asked to complete the questionnaire of personal data, the Spielberger Anxiety Inventory and McGill Pain Questionnaire.

Settings and conduct

After confirmation of the patient's condition, after the surgery, with the approval of orthopedic surgeon, progressive muscle relaxation will be trained to the intervention group, the intervention group, in the orthopedic department, daily, 3 times a day, and each The load will be carried out 10 to 20 times before clearance, then the questionnaires will be resubmitted by both groups.

Participants/Inclusion and exclusion criteria

Outcome criteria: history of performing a relaxation technique within six months, use of muscle relaxant, hypnotic and psychoactive drugs. Measure: Inclination to participate in intervention. Defeat in the lower extremities - Pain score less than 6 and minimum anxiety score of 20

Intervention groups

The intervention group will receive a progressive muscle relaxant technique. Control group: no intervention will be received.

Main outcome variables

Pain, Anxiety

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20180212038701N1**

Registration date: **2018-08-03, 1397/05/12**

Registration timing: **prospective**

Last update: **2018-08-03, 1397/05/12**

Update count: **0**

Registration date

2018-08-03, 1397/05/12

Registrant information

Name

Hanie Dahmardeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3328 1359

Email address

h.dahmardeh@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-21, 1397/06/30

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of progressive muscle relaxation technique on pain and anxiety of patients undergoing orthopedic

surgery

Public title
The effect of progressive muscle relaxation technique on pain and anxiety of patients undergoing orthopedic surgery in 2017

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Inclination to participate in intervention Fractures in the lower extremities Having pain due to illness or its treatment Being alert and educable Having read and write skills to complete the research questionnaires, Score less than 6 points Minimum anxiety score of 20. fracture diagnosis by the orthopedic surgeon confirmation of the need for orthopedic surgeries by the orthopedic surgeon
Exclusion criteria:
History of performing a relaxation technique or specific exercise during the past six months, Use of muscle relaxant, hypnotic and psychoactive drugs

Age
From **12 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method is simple randomization, randomization unit, individuals, and the randomization tool of random numbers.

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 Zahedan University of Medical Sciences

Street address

Dr. Hesabi Square- Medical Sciences Campus-

Zahedan -Iran
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2018-01-14, 1396/10/24
Ethics committee reference number
IR. ZAUMS. REC.1396.332

Health conditions studied

1

Description of health condition studied

Fracture

ICD-10 code

M96.6

ICD-10 code description

Fracture of bone following insertion of orthopaedic implant, joint prosthesis, or bone plate

Primary outcomes

1

Description

Severity of Anxiety

Timepoint

Before the intervention - after the discharge of patients from the department

Method of measurement

Spillbugger's Secret and Detecting Anxiety Inventory (STAI)

2

Description

Severity of Pain

Timepoint

Before the intervention - after the discharge of patients from the department

Method of measurement

The McGill Pain Questionnaire (MPQ)

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description

Intervention group: On the first day, after the patient's

condition is confirmed, with the approval of the orthopedic surgeon and the condition of the patient, progressive muscle relaxation will be taught to the intervention group and the intervention will begin, for this purpose, a program The training will be designed and implemented in 7 stages for patients, the stages of which are: recognition of muscles and muscle groups, training on the progress of muscle development techniques using the explanation and practical demonstration by the researcher, responsiveness Questions to clients about relaxation techniques, implementation of techniques by the researcher Then, this technique will be performed by intervention group samples after surgery, daily and 3 times a day, and each time between 10 and 20 times before the discharge, then the questionnaires will be completed again. The progressive muscle relaxation technique trained to patients will be performed by them, then will be performed by the patients throughout the day.

Category

Rehabilitation

2

Description

Control group: For patients in the orthopedic routine care control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Al-Anbia Hospital

Full name of responsible person

Hanie Dahmardeh

Street address

Alborz28-Zibashahr

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817964884

Phone

+98 54 3328 1359

Email

haniedahmardeh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Hanie Dahmardeh

Street address

Medical Sciences Campus, Dr. Hesabi Square, Zahedan, Iran

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3329 5744

Email

haniedahmardeh@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahedan 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

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Hanie Dahmardeh

Position

Academic instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Alborz 28-Zibashahr

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817964884

Phone

+98 54 3328 1359

Email

haniedahmardeh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences
Full name of responsible person
Hanie Dahmardeh
Position
Academic instructor
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Alborz 28-Zibashahr
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9817964884
Phone
+98 54 3328 1359
Email
haniedahmardeh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Hanie Dahmardeh
Position
Academic instructor
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Alborz 28 - Zibashahr
City
Zahedan
Province
Sistan-va-Balouchestan

Postal code
9817964884
Phone
+54 33281359
Email
haniedahmardeh@gmail.com

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

Confidentiality of the participants' information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data will be released after analysis

When the data will become available and for how long

After the intervention and data analysis

To whom data/document is available

Researcher - collaborator

Under which criteria data/document could be used

If requested by other people who intend to do the same research, the analyzed data will be provided to them.

From where data/document is obtainable

Email the researcher

What processes are involved for a request to access data/document

Email the researcher

Comments