# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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**