

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Examining the effect of progressive muscle relaxation technique on postoperative pain, sleep quality, and anxiety in hospitalized patients with hip fractures

Protocol summary

Study aim

Determining the effect of progressive muscle relaxation on the amount of pain, sleep quality and anxiety of hospitalized patients with hip fracture

Design

The study is a one-blind clinical trial study conducted on 100 patients with hip fractures eligible to enter the study and assigned randomly individual assigned to the intervention group (50 people) and control group (50 people) using coin toss. Intervention is a progressive muscle relaxation technique that will be performed for three consecutive nights starting tomorrow night after surgery.

Settings and conduct

The study will be conducted at Shohaie_Haftome_Tir hospital, Tehran. The study is a one-blinded and participants will not be informed about group assignment. Participants were assigned to the intervention group (50 people) and control (50 people) based on entry criteria and individual randomization (coin toss). The two groups were matched in terms of receiving pain relief, and all of them will receive Apotel painkillers as directed by the doctor. The progressive muscle relaxation technique started the night after the surgery and will continue for three days. The intervention will be implemented by the first researcher. The data will be measured in two phases including before the intervention and one day after the intervention is completed.

Participants/Inclusion and exclusion criteria

Confirmed hip fracture; Age 40-65; Hospitalization for at least 5 days; Not having multiple fractures in the limbs; Having literacy; Not using sleeping pills, antidepressants, and psychosis; Not having dementia; No drug addiction

Intervention groups

Progressive muscle relaxation technique for intervention group participants started one night after surgery and

will continue for three consecutive nights. The control group will not receive such an intervention.

Main outcome variables

Postoperative pain; Sleep quality; Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231120060119N1**

Registration date: **2023-12-07, 1402/09/16**

Registration timing: **prospective**

Last update: **2023-12-07, 1402/09/16**

Update count: **0**

Registration date

2023-12-07, 1402/09/16

Registrant information

Name

Sahar Mashhadinaser

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5598 3306

Email address

sahari77.nasari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Examining the effect of progressive muscle relaxation technique on postoperative pain, sleep quality, and anxiety in hospitalized patients with hip fractures

Public title
Effect of progressive muscle relaxation technique on postoperative pain sleep quality, and anxiety in hospitalized patients with hip fractures

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of hip fractures (based on the diagnosis of an orthopedic specialist in the medical record) age 40-65 No multiple trauma or fracture of both upper and lower limbs Being literate in reading and writing No use of sleeping, sedative anti-depressant, or psychotic drugs in the last 2 months No serious dementia or cognitive dysfunction (based on the patient's or his family's self-report) No drug addiction

Exclusion criteria:
Dissatisfaction to enter the study Hospitalization less than 5 days Hospitalization less than 48 hours from admission

Age
From **40 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Hip fracture patients who are eligible will be assigned to intervention and control groups by individual randomness and using coin toss (lion/line). This sampling process continues until at least 50 people enter each group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The analyzer is not aware of which of the two intervention or control groups the data belongs to.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Beheshti University of Medical Sciences
Street address
Vali-Asr Street
City
Tehran
Province
Tehran
Postal code
1996835119

Approval date
2023-02-12, 1401/11/23

Ethics committee reference number
IR.SBMU.RETECH.REC.1401.724

Health conditions studied

1

Description of health condition studied
Hip fracture
ICD-10 code
M80-M85
ICD-10 code description
Disorders of bone density and structure

Primary outcomes

1

Description
Sleep quality
Timepoint
Before the intervention, one day after the completion of the intervention
Method of measurement
Numerical rating scale for pain

2

Description
Sleep quality
Timepoint
The Pittsburgh Sleep Quality Index
Method of measurement
Before the intervention, one day after the completion of the intervention

3

Description
Anxiety
Timepoint

Before the intervention, one day after the completion of the intervention

Method of measurement

The State-Trait Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: the group will receive progressive muscle relaxation from the next day of surgery for three nights, while the last meal has been at least three hours. Each time, the process will take about 30 minutes. At the stage of preparation for the technique, the room's environment will be calmed down, and environmental stimuli will be minimized. The trainee participant will be asked to go to the bathroom, empty his bladder, dress loosely, take off his socks and shoes, lie on his back comfortably, minimize using five senses, and close his eyes. In the implementation phase, the participant is trained to contract each muscle of the upper limbs, shoulders, head and neck, chest, abdomen, and lower limbs for 15-10 seconds, respecting the order, and then relax for 15-20 seconds. At the same time as the exercises, the participant will be taught to exhale through the nose, the deep tail, and the mouth. If the contributor starts from the left upper limb and then moves to the right limb, they can also follow this principle for other movements. Each group of muscles will train back to back three times in a row.

Category

Behavior

2

Description

Control group: will not receive any intervention in the form of progressive muscle relaxation.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Haftome_Tir hospital

Full name of responsible person

Dr Seyed Abdolhadi Daneshi

Street address

Shahid Rejaee Street

City

Tehran

Province

Tehran

Postal code

252634897

Phone

+98 21 5522 8582

Fax

+98 21 5521 7901

Email

web7tir@iums.ac.ir

Web page address

https://hosph.t.iums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Alireza Zali

Street address

Velenjak, Daneshjoo Boulevard, the Arabi street

City

Tehran

Province

Tehran

Postal code

8877644421

Phone

+98 21 2243 9780

Fax

Email

info@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

50

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Parvaneh Vasli

Position

Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Valiasr Street

City

Tehran

Province

Tehran

Postal code

1996835119

Phone

+98 21 8865 5367

Email

parvanehvasli@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Parvaneh Vasli

Position

Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Valiasr Street

City

Tehran

Province

Tehran

Postal code

1996835119

Phone

+98 21 8865 5367

Email

parvanehvasli@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Parvaneh Vasli

Position

Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Valiasr Street

City

Tehran

Province

Tehran

Postal code

1996835119

Phone

+98 21 8865 5367

Email

parvanehvasli@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

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

The data will be kept in the form of an SPSS file with the corresponding author and made available to readers upon request. The results of the data analysis will also be published in a scientific journal.

When the data will become available and for how long

After the article was published

To whom data/document is available

Any reader of the published article who requests

Under which criteria data/document could be used

Whenever readers request.

From where data/document is obtainable

The corresponding author

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

Send an email to the corresponding author to request the data

Comments