Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Sahar Mashhadinaser

Name of organization / entity

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Iran (Islamic Republic of)

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Alireza Zali

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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

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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