Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Progressive Muscle Relaxation on Fatigue, Functional Ability, and Health Anxiety in Hospitalized Patients after Ischemic Stroke

Protocol summary

Study aim

To determine and compare the mean fatigue,functional ability,health anxiety scores of patients with ischemic stroke at three stages (pre, post-test, and 4-week follow-up) between the intervention and control groups .

Design

study is a randomized, controlled, single-blind clinical trial with two parallel groups and a 4-week follow-up period, conducted on 120 patients. For randomization, a set of sealed envelopes containing predetermined numbers will be placed in a bag. A staff member will randomly select one envelope for each patient. Based on the assigned number, patients with even numbers will be allocated to the control group (receiving routine care), whereas those with odd numbers will be assigned to the intervention group (receiving progressive muscle relaxation).

Settings and conduct

The training sessions will be delivered individually, face-to-face, once daily during the morning shift, and will last approximately 20–30 minutes at the patient’s bedside in the neurology ward of Ali ibn Abi Talib and Khatam al-Anbia Hospitals in Zahedan. Each session involves the sequential tensing and relaxing of different muscle groups.This group will receive only routine ward care and no additional interventions.

Participants/Inclusion and exclusion criteria

First occurrence of ischemic stroke Age range between 20 and 80 years NIHSS score < 12 Ability to read and write No history of central nervous system disorders such as dementia, Parkinson’s disease, or seizures prior to the stroke No history of psychiatric disorders Accessibility and availability of the patient throughout the study period

Intervention groups

The intervention group will undergo progressive muscle relaxation training conducted by a trained researcher for five consecutive days. control group will receive only routine ward care and no additional interventions.

Main outcome variables

Fatigue, Functional Ability, Health Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251022067726N1**
Registration date: **2025-11-12, 1404/08/21**
Registration timing: **prospective**

Last update: **2025-11-12, 1404/08/21**
Update count: **0**

Registration date

2025-11-12, 1404/08/21

Registrant information

Name

Mehdi Rezvani amin

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-29, 1404/09/08

Expected recruitment end date

2026-03-20, 1404/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of Progressive Muscle Relaxation on Fatigue, Functional Ability, and Health Anxiety in Hospitalized Patients after Ischemic Stroke

Public title
The Effect of Progressive Muscle Relaxation on Fatigue, Functional Ability, and Health Anxiety in Patients after Ischemic Stroke

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with confirmed diagnosis of ischemic stroke
Exclusion criteria:
First occurrence of ischemic stroke Age range between 20 and 80 years NIHSS score < 12 Ability to read and write No history of central nervous system disorders No history of psychiatric disorders Accessibility and availability of the patient throughout the study period

Age
From **20 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **120**
More than 1 sample in each individual
Number of samples in each individual: **4**
Each participant will complete the FIS, SIS, and SHAI questionnaires as self-report instruments. Additionally, the Barthel Index will be completed for all participants by an independent assessor.

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, patients diagnosed with ischemic stroke who meet the inclusion criteria will be selected using a convenience sampling method upon admission to the ward. After obtaining written informed consent, each eligible patient will be enrolled as a participant in the study. The allocation of patients into the intervention and control groups will be performed randomly and immediately after admission. To achieve this, a number of sealed envelopes containing pre-assigned numbers will be placed in a bag, and one of the ward staff members will randomly draw an envelope for each patient. Based on the assigned number, patients with even numbers will be allocated to the control group (receiving routine care), while those with odd numbers will be allocated to the intervention group (receiving progressive muscle relaxation training). The randomization process will be conducted at the time of hospitalization and prior to the initiation of any intervention to prevent allocation bias and ensure baseline balance between the study groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the functional ability of patients in both the intervention and control groups will be assessed on the first day of hospitalization, on the fifth day of hospitalization at the time of discharge, and again four weeks after discharge. Functional status will be measured using the Barthel Index through direct observation or patient interview (and when communication difficulties are present, through an informed caregiver). All assessments will be conducted by an independent evaluator, selected from among master's-level nursing students, who will be blinded to the study details (Blinded Assessor) in order to minimize bias in data collection.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Zahedan University of Medical sciences

Street address
Zahedan University of Medical Sciences, Kaj Blvd., Emam Hossein Blvd

City
zahdan

Province
Sistan-va-Balouchestan

Postal code
9816743111

Approval date
2025-10-21, 1404/07/29

Ethics committee reference number
IR.ZAUMS.REC.1404.273

Health conditions studied

1

Description of health condition studied
Ischemic Stroke

ICD-10 code
I63

ICD-10 code description
Cerebral infarction

Primary outcomes

1

Description
fatigue
Timepoint
Fatigue will be measured at baseline (prior to the initiation of the intervention), as well as on days 5 and 33 following the progressive muscle relaxation intervention.
Method of measurement
Fatigue Impact Scale

2

Description
Functional Ability
Timepoint
Functional Ability will be measured at baseline (prior to the initiation of the intervention), as well as on days 5 and 33 following the progressive muscle relaxation intervention.
Method of measurement
Barthel and Stroke Impact Scale

3

Description
Health Anxiety
Timepoint
Health Anxiety will be measured at baseline (prior to the initiation of the intervention), as well as on days 5 and 33 following the progressive muscle relaxation intervention.
Method of measurement
Short Health Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group will undergo progressive muscle relaxation (PMR) training conducted by a trained researcher for five consecutive days. The training sessions will be delivered individually, face-to-face, once daily during the morning shift, and will last approximately 20–30 minutes at the patient's bedside in the neurology ward. Each session involves the sequential tensing and relaxing of different muscle groups. Patients will be positioned supine, and the exercises will be performed in the following order:1. Raise the eyebrows.2. Close the eyes tightly.3. Clench the jaw and pull the corners of the mouth backward.4. Bring the chin toward the chest (without contact).5. Make a fist with the dominant hand.6. Press the dominant elbow against the body.7. Make a fist with the non-dominant hand.8. Press the non-dominant elbow against the body.9. Pull the shoulders backward, take a deep breath, and hold it.10. Contract the abdomen.11. Lift the dominant leg slightly off the bed and hold.12. Point the toes of the dominant foot upward.13. Flex the toes of the dominant foot toward the sole and then release.14. Lift the non-dominant leg slightly off the bed and hold.15. Point the toes of the non-dominant foot upward.16. Flex the toes of the non-dominant foot toward the sole and then release.Each muscle group will be tensed for 10 seconds and then relaxed for 20–30 seconds . This cycle will be repeated twice for each muscle during every session. Prior to conducting the intervention, the researcher received both theoretical and practical training in progressive muscle relaxation (PMR) under the supervision of a specialist in physical medicine and lifestyle modification and holds a certification in the technique. The exercises will be conducted by the trained researcher following a standardized checklist , and all sessions will be documented in a session log, including start and end times, patient cooperation, and any adverse events or complications such as dizziness, muscle pain, or others. Any serious adverse event attributable to the study will be reported promptly to the Ethics Committee and other relevant legal authorities.
Category
Rehabilitation

2

Description
Control group: will receive only routine ward care and no additional interventions.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali Ibn Abi Talib Hospitals in Zahedan
Full name of responsible person
Kaveh Orei Yazdani
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2

Recruitment center
Name of recruitment center
Khatam Al-Anbia Hospitals in Zahedan
Full name of responsible person
Mohammadreza Miradi

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Sponsors / Funding sources

1

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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
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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available