

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Effects of Vestibular Rehabilitation Interventions on Fatigue, Depression, and Activities of Daily Living in Armed Forces Retirees with Stroke: A Randomized Controlled Trial Study

Protocol summary

Study aim

Effects of Vestibular Rehabilitation Interventions on Fatigue, Depression, and Activities of Daily Living in Armed Forces Retirees with Stroke: A Randomized Controlled Trial Study

Design

A single randomized clinical trial, with a parallel group of 25 patients

Settings and conduct

Sampling from Hospitals affiliated with the Aja University of Medical Sciences (in Tehran city) is done. After the eligible patients fill out the consent form, they will be randomly assigned to two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: History of Only one cerebrovascular accident At least a score of 21 in the Mini-mental state examination(MMSE) absence of severe visual and auditory disorders; lack of diabetes; osteoarthritis and osteoporosis, especially in the lower limbs; any other neurological disease The ability to walk with or without auxiliary equipment Exclusion criteria: Failure to cooperate with the patient during tests and exercises Failure to return a patient to perform second-stage tests after interventions Patients who change their medication regimen during the intervention

Intervention groups

Two groups: 1) control group (Common Rehabilitation Interventions), 2) intervention group (Common Rehabilitation Interventions+Vestibular Rehabilitation Interventions)

Main outcome variables

Fatigue, Depression, and Activities of Daily Living

General information

Reason for update

1- In order to measure the patient's ability, the ability to

walk with and without an aid device as one of the criteria for inclusion in the study was supplemented by adding the Functional Ambulation Classification test. 2- Due to the implementation of interventions on stroke patients suffering from fatigue, the inclusion criteria for fatigue assessment based on the Fatigue Assessment Scale was added. 3- In the primary outcomes section, in addition to the Fatigue Impact Scale, the Fatigue Assessment Scale was added to the questionnaires to evaluate the effect of vestibular rehabilitation interventions on fatigue in order to increase the validity and effectiveness of the interventions. 4- Due to the small number of available samples (Armed Forces retirees with stroke) for two primary outcomes simultaneously (fatigue and depression together), the depression variable was transferred from the primary outcomes section to the secondary outcomes section.

Acronym

IRCT registration information

IRCT registration number: **IRCT20090904002415N3**

Registration date: **2022-01-10, 1400/10/20**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-18, 1401/01/29**

Update count: **1**

Registration date

2022-01-10, 1400/10/20

Registrant information

Name

Bahador Asadi Khansari

Name of organization / entity

Army University of Medical Science

Country

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Recruitment status**Recruitment complete****Funding source****Expected recruitment start date**

2021-12-26, 1400/10/05

Expected recruitment end date

2022-04-19, 1401/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Vestibular Rehabilitation Interventions on Fatigue, Depression, and Activities of Daily Living in Armed Forces Retirees with Stroke: A Randomized Controlled Trial Study

Public title

The Effects of Vestibular Rehabilitation on Stroke Patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

History of Only one cerebrovascular accident At least a score of 21 in Mini-mental state examination(MMSE) absence of severe visual and auditory disorders; lack of diabetes; osteoarthritis and osteoporosis, especially in the lower limbs; any other neurological disease The ability to walk with or without auxiliary equipment (score of 3 or higher in the Functional Ambulation Classification) Score more than 24 on the Fatigue Assessment Scale

Exclusion criteria:

Failure to co-operate with the patient during tests and exercises Failure to return a patient to perform second-stage tests after interventions Patients who change their medication regimen during the intervention

AgeFrom **40 years** old to **90 years** old**Gender**

Male

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample sizeTarget sample size: **50****Randomization (investigator's opinion)**

Randomized

Randomization description

Available samples of stroke patients referred to Golestan and Imam Reza hospitals affiliated to Aja University of Medical Sciences in Tehran selected according to the selected inclusion criteria and after agreeing to participate in this study and signing the consent form, they will be divided into two groups of control and intervention by complete randomization method (sealed

envelope method). In absolute random method (envelope and paper method), the name of groups will be written on a piece of paper and put in an envelope and the participants will be asked to choose one of the papers randomly then the patient will be placed in the intervention or control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Outcome evaluator: The person or people who evaluate the outcome or non-outcome of the outcome in the participants or collect data on the outcome variables. In this study, All primary and secondary assessments are performed by an experienced occupational therapist working with stroke patients who have already been taught the tests by the researcher and are completely blind to the type of intervention in both intervention and control groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Aja University of Medical Sciences

Street address

Fatemi St., Etemadzadeh St., Army University of Medical Sciences, Ethics Committee

City

Tehran

Province

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Postal code

1411718541

Approval date

2021-12-22, 1400/10/01

Ethics committee reference number

IR.AJAUMS.REC.1400.245

Health conditions studied**1****Description of health condition studied**

Stroke

ICD-10 code

I67

ICD-10 code description

Other cerebrovascular diseases

Primary outcomes

1

Description

Fatigue

Timepoint

Before intervention, after intervention

Method of measurement

Fatigue Impact Scale, Fatigue assessment scale

Secondary outcomes

1

Description

Independence in the activities of daily living

Timepoint

Before and after the intervention

Method of measurement

Barthel Index (Independence in Basic Activities of Daily Living) and Lawton IADL Scale (Independence in Instrumental of Daily Living)

2

Description

Depression

Timepoint

Before intervention, after intervention

Method of measurement

Beck Depression Inventory

Intervention groups

1

Description

Intervention group: In addition to routine rehabilitation exercises, they receive vestibular rehabilitation interventions that include a 26-exercise protocol classified into five general sections. These five sections include body exercises without standing on the ground, body in half-kneeling on the ground, body standing on a trampoline, walking, and finally exercises related to eye movements.

Category

Rehabilitation

2

Description

Control group: Routine rehabilitation exercises include muscle stretching, positioning, muscle strengthening, and range of motion exercises.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Bahador Asadi Khansari

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Sayad Shirazi Highway, Pasdaran St. (5th Golestan),

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2

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Mojtaba Yousefi Zashk

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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
Artesh 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
Artesh University of Medical Sciences

Full name of responsible person
Amin Ghaffari

Position
Elite

Latest degree
Master

Other areas of specialty/work
Occupational Therapy

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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

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Not Decided

When the data will become available and for how long

Not Decided

To whom data/document is available

Not Decided

Under which criteria data/document could be used

Not Decided
From where data/document is obtainable
Not Decided
What processes are involved for a request to access

data/document
Not Decided
Comments