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 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

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

Iran (Islamic Republic of)

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Email address

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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
Age
From **40 years** old to **90 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target 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
Tehran
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
Street address
Sayad Shirazi Highway, Pasdaran St. (5th Golestan),
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1668619551
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peiman_asadi@ajaums.ac.ir

2

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Bahador Asadi Khansari
Street address
North Shahid Etemadzadeh St., West Fatemi St.
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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
Street address
Aja University of Medical Sciences, Etemadzadeh St.,Fatemi St.
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peiman_asadi@ajaums.ac.ir
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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Elite Circle, Aja University of Medical Sciences, Etemadzadeh St.,Fatemi St.

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Person responsible for scientific inquiries

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Assistant Professor

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Neurology

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Person responsible for updating data

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Position
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Other areas of specialty/work
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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