Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effect of Repetitive Facilitative Exercise (RFE) Combined with Action Observation (AO) on Upper Extremity Motor Function in Stroke Patients

Protocol summary

Study aim

Effect of Repetitive Facilitatory Exercises Combined with Action Observation on Upper Limb and Functional Performance motor After Stroke

Design

This study is a single-group quasi-experimental interventional study with a pretest–posttest design, using convenience sampling without random allocation or a control group. Outcomes will be assessed before and after the intervention.

Settings and conduct

Participants will be recruited through convenience sampling from selected hospitals, occupational therapy clinics, and rehabilitation centers in Tehran and Karaj. The intervention will be administered by the principal investigator.

Participants/Inclusion and exclusion criteria

Inclusion: Age 30–75 y; 3 months–5 years post ischemic/hemorrhagic stroke with upper-limb motor impairment; medically stable; Reading and writing literacy; stage ≥3; stable sitting; MoCA ≥22; adequate vision; written informed consent. Exclusion: Visuospatial or unilateral neglect; Severe joint contractures lead to restricted limb mobility and chronic conditions, including orthopedic, neurological, and metabolic disorders, as well as addiction and diabetes, ...; botulinum toxin injection within 3 months before enrollment or planned during intervention. Withdrawal: Recurrent stroke during intervention; unwillingness to continue treatment.

Intervention groups

Ten participants will receive 18 sessions over 6 weeks (3 sessions/week, 45 minutes/session), comprising 30 minutes of Repetitive Facilitative Exercise followed by 15 minutes of Action Observation and targeted upper extremity task practice.

Main outcome variables

Study outcomes include upper extremity motor function by the Fugl-Meyer Assessment, functional performance by the Action Research Arm Test, arm and hand functional ability by the Chedoke Arm and Hand Activity Inventory-13, and affected-arm use and movement quality in daily activities by the Motor Activity Log.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140416017301N10**
Registration date: **2026-09-16, 1405/06/25**
Registration timing: **prospective**

Last update: **2026-09-16, 1405/06/25**
Update count: **0**

Registration date

2026-09-16, 1405/06/25

Registrant information

Name

Akram Azad

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-11-22, 1405/09/01

Expected recruitment end date

2027-11-21, 1406/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Repetitive Facilitative Exercise (RFE) Combined with Action Observation (AO) on Upper Extremity Motor Function in Stroke Patients

Public title

Effect of Repetitive Facilitative Exercise Combined with Action Observation on Upper Limb Function in Stroke Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of ischemic or hemorrhagic stroke with upper extremity motor impairment (based on medical records and/or brain imaging). Ability to maintain a stable sitting position for participation in training and assessment. At least 3 months and a maximum of 5 years have passed since stroke onset. Age between 30 and 75 years. Being at Brunnstrom stage 3 or higher of upper extremity motor recovery. Medical stability and ability to participate in the rehabilitation program. Having a minimum cognitive function score of 22 based on the MoCA test. Sufficient visual ability, with or without corrective aids, to observe video content Written informed consent for participation in the study. Education level: basic literacy (reading and writing)

Exclusion criteria:

Severe contracture impairing limb movement Comorbid chronic conditions, such as orthopedic, neurological, and metabolic disorders, addiction, and diabetes Severe visual field defects or severe visuospatial neglect Unilateral neglect Receiving botulinum toxin injection in the affected upper extremity within 3 months before study entry Decision to get a botulinum toxin injection during the intervention period

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees Certificate

Street address

School of Rehabilitation. Nazari Ave. Madar Sq. Mirdamad Blvd. Tehran City

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Tehran

Province

Tehran

Postal code

154591-3187

Approval date

2026-08-18, 1405/05/27

Ethics committee reference number

IR.IUMS.REHAB.REC.1405.022

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

I69

ICD-10 code description

Sequelae of cerebrovascular disease

Primary outcomes

1

Description

Motor function score of the affected upper extremity assessed by the upper extremity section of the Fugl-Meyer Assessment

Timepoint

Before the intervention at pre-test and after completion of the six-week intervention at post-test

Method of measurement

Upper extremity section of the Fugl-Meyer Assessment

Secondary outcomes

1

Description

Upper extremity functional performance score based on the Action Research Arm Test

Timepoint

Before the intervention at pre-test and after completion of the six-week intervention at post-test

Method of measurement

Action Research Arm Test

2

Description
Amount of use and quality of movement scores of the affected upper extremity in daily activities based on the Motor Activity Log
Timepoint
Before the intervention at pre-test and after completion of the six-week intervention at post-test
Method of measurement
Motor Activity Log

3

Description
Upper extremity functional ability score based on the Chedoke Arm and Hand Activity Inventory-13 (CAHAI-13)
Timepoint
Before the intervention at pre-test and after completion of the six-week intervention at post-test
Method of measurement
Chedoke Arm and Hand Activity Inventory (CAHAI-13)

Intervention groups

1

Description
Intervention group: All participants will receive a combined intervention consisting of Repetitive Facilitative Exercises and Action Observation for 6 weeks, three sessions per week, for a total of 18 sessions. Each session will last 45 minutes and will be delivered by the principal investigator. During the first 30 minutes of each session, Repetitive Facilitative Exercises will be performed to facilitate voluntary movement and improve motor function of the affected upper extremity. Participants will repeatedly perform targeted voluntary upper-extremity movements while the therapist simultaneously applies facilitative stimuli, including rapid stretch of the target muscle and rapid cutaneous stimulation. The exercises will involve the shoulder, elbow, wrist, and fingers. The subsequent 15 minutes of each session will be devoted to Action Observation. During this component, the participant will first observe a step-by-step video demonstration of a targeted upper-extremity movement or functional task and will then attempt to perform the same movement or task with the affected upper extremity according to his or her motor ability. The videos will be prepared by the researcher before the start of the study in accordance with the objectives and content of the intervention protocol and will include functional upper-extremity tasks such as reaching for objects, grasping, transferring, and releasing objects. The overall intervention framework will be identical for all participants; however, task selection, level of difficulty, amount of therapist assistance, and progression of training will be individually adjusted according to each participant's motor status, response, and ability. Exercise intensity will also be modified according to the participant's tolerance and clinical condition.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of the School of Rehabilitation Sciences, Iran University of Medical Sciences; Firoozgar Hosp
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Afsoon Hassani Mehraban
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School of Rehabilitation Sciences, Shahnazari St., Madar Sq., Mirdamad Blvd., Tehran, Iran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Research Deputy, School of Rehabilitation Sciences, Iran 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
Iran University of Medical Sciences
Full name of responsible person
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Position
PhD of Occupational Therapy, Professor and Faculty Member, Department of Occupational Therapy
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Individual participant data will not be publicly shared because the current informed consent and ethics plan do not provide for public sharing of participant-level data. Study results will be reported only in aggregate form without identifying information.
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable