Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluating The effectiveness of bilateral versus unilateral robotic glove-assisted training on hand motor function and functional independence in stroke patients with unilateral involvement

Protocol summary

Study aim

To compare the effects of bilateral and unilateral robotic-glove-assisted hand exercises on hand motor function and functional independence in

Design

This study is a randomized parallel-group clinical trial in which 44 eligible patients will be randomly allocated using block randomization into two intervention groups: bilateral training using a robotic glove and unilateral training using a robotic glove. The sample size was calculated based on 80% power, a 0.05 significance level, and a moderate effect size.

Settings and conduct

This randomized clinical trial will be conducted on patients with stroke. Eligible participants will be enrolled after obtaining written informed consent and will be randomly allocated into two intervention groups. Rehabilitation interventions will be performed at the Comprehensive Rehabilitation Clinic of Mashhad University of Medical Sciences. Outcome assessments will be performed by an independent assessor blinded to group allocation, and statistical analysis will be conducted by a person blinded to the group assignments

Participants/Inclusion and exclusion criteria

Inclusion criteria were patients with unilateral ischemic stroke aged 20–75 years, at least three months post-stroke, with the ability to understand and follow instructions and without severe spasticity. Exclusion criteria included other neurological disorders, upper limb fractures, concurrent participation in other rehabilitation or drug studies, and botulinum toxin injection within the past three months

Intervention groups

Intervention Group 1: bilateral training using a robotic glove Intervention Group 2: unilateral training using a robotic glove

Main outcome variables

The primary outcome of this study is upper limb motor function, which will be assessed using the Upper Extremity section of the Fugl-Meyer Assessment (FMA-UE) before and after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221019056245N4**
Registration date: **2026-08-05, 1405/05/14**
Registration timing: **prospective**

Last update: **2026-08-05, 1405/05/14**
Update count: **0**

Registration date

2026-08-05, 1405/05/14

Registrant information

Name

Khodabakhsh Javanshir

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-08-22, 1405/05/31

Expected recruitment end date

2026-10-22, 1405/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating The effectiveness of bilateral versus unilateral robotic glove-assisted training on hand motor function and functional independence in stroke patients with unilateral involvement

Public title

Comparing one-hand and two-hand robotic glove exercises to improve hand movement in stroke patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with ischemic stroke At least three months have passed since the onset of stroke Age between 20 and 75 years The patient must be able to understand and follow the therapists instructions as assessed by the Minimal-Mental State Examination No severe spasticity(Modified Ashworth Scale)

Exclusion criteria:

Patients with a history of other neurological disorders, such as peripheral polyneuropathy, will be excluded from the study. Patients with a history of fracture of the upper limb or hand will be excluded from the study. Patients who are simultaneously participating in other pharmacological or rehabilitation studies will be excluded from the study. Patients who have received botulinum toxin injections within the past three months will be excluded from the study.

Age

From **20 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible participants will be randomly allocated to either the bilateral robotic glove training group or the unilateral robotic glove training group using block randomization after obtaining informed consent. The unit of randomization will be the individual participant. A computer-generated random sequence will be used for randomization. Allocation concealment will be ensured using sealed, opaque, sequentially numbered envelopes.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the intervention, complete blinding of participants and therapists is not feasible. Participants will not be aware of their assigned group prior to the initiation of the intervention; however, they will become aware of the type of training after the intervention begins. Outcome assessors will be blinded to group allocation. In addition, statistical analysis will be performed by an analyst who is blinded to group allocation.

Placebo

Not used

Assignment

Parallel

Other design features

This study does not have any unique design features beyond those already described in the previous sections

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

Street address

Ganj afrooz St.

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2025-12-08, 1404/09/17

Ethics committee reference number

IR.MUBABOL.REC.1404.187

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

n this study, upper limb motor function is considered the primary outcome and will be assessed using the Upper Extremity section of the Fugl-Meyer Assessment (FMA-UE). Assessments will be performed before and after the intervention period.

Timepoint
Primary outcome will be assessed at two time points: before the intervention and immediately after completion of the intervention period.

Method of measurement
Upper limb motor function will be measured using the Upper Extremity section of the Fugl-Meyer Assessment (FMA-UE). All assessments will be performed by a trained and independent assessor who is blinded to group allocation, before and after the intervention.

Secondary outcomes

1

Description
The secondary outcome of this study is functional independence, which will be assessed using the Functional Independence Measure (FIM). This measure reflects the level of independence in activities of daily living and will be evaluated before and after the intervention period.

Timepoint
The secondary outcome will be assessed at two time points: before the intervention and immediately after completion of the intervention period.

Method of measurement
Functional independence as the secondary outcome will be measured using the Functional Independence Measure (FIM). Assessments will be conducted by a trained and independent assessor blinded to group allocation, before and after the intervention.

Intervention groups

1

Description
Intervention group:Group 1 (Bilateral training using a robotic glove):Participants in this group will receive 12 rehabilitation sessions over one month (three sessions per week). Each session consists of two phases:1.Ten minutes of conventional physiotherapy including stretching, weight-bearing, and range of motion exercises 2. Robotic glove training consisting of two types of exercises:1.Finger opening and closing 2.Finger opposition movements. Each exercise will be repeated 100 times. The robotic glove exercises are performed with both hands simultaneously.Group 2 (Unilateral training using a robotic glove):Participants in this group will receive 12 rehabilitation sessions similar to Group 1. The session sequence and duration are the same (ten minutes of physiotherapy followed by robotic glove training). The difference is that robotic glove exercises are performed only with the affected hand, including finger opening and closing and finger opposition, each repeated 100 times.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Comprehensive Rehabilitation Center

Full name of responsible person
Hossein Negahban

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Sponsors / Funding sources

1

Sponsor

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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
Babol 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

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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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available