Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effectiveness of Visual Rehabilitation Interventions on Activities of Daily living and Cognition of People with Stroke

Protocol summary

Study aim
Effectiveness of visual rehabilitation interventions on activities of daily living and cognition in stroke patients.

Design
A single-blind, randomized controlled clinical trial with a parallel-group design, utilizing permuted block randomization (Phase 2-3) on 40 patients.

Settings and conduct
Location: Occupational Therapy clinic, school of Rehabilitation, Tehran University of Medical Sciences. Method: After obtaining the necessary approvals, eligible participants will provide both written and oral informed consent. They will then be randomly assigned, using a permuted block design (10 blocks of 4 participants), to either the intervention or the control group. The control group will receive only conventional occupational therapy interventions, while the intervention group will receive, in addition, visual rehabilitation interventions based on Warren's hierarchical visual processing model. The treatment course consists of 12 sessions (3 sessions per week). After the completion of the interventions, all data will be analyzed using SPSS 27. Blinding: Both the evaluator and the statistical analyst will be blinded; this blinding will be implemented using a coding method.

Participants/Inclusion and exclusion criteria
Individuals aged 24 to 65 with a history of only one stroke (1 to 6 months post-stroke), a minimum visual acuity of 20/60, an MMSE score between 10 and 23, a TVPS score below 85, and the ability to follow instructions and complete assessments.

Intervention groups
The control group will receive only conventional occupational therapy interventions, while the intervention group will receive visual rehabilitation interventions alongside conventional occupational therapy interventions.

Main outcome variables
oculomotor, visual perception, visual-motor integration, cognition, activities of daily living

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250216064740N1**
Registration date: **2025-02-27, 1403/12/09**
Registration timing: **prospective**

Last update: **2025-02-27, 1403/12/09**
Update count: **0**

Registration date
2025-02-27, 1403/12/09

Registrant information

Name
Amin MansourLakouraj

Name of organization / entity

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Iran (Islamic Republic of)

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+98 21 7753 3939

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-06, 1404/01/17

Expected recruitment end date
2025-09-21, 1404/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The Effectiveness of Visual Rehabilitation Interventions on Activities of Daily living and Cognition of People with Stroke

Public title
The Effectiveness of Visual Rehabilitation on Activities of Daily living and Cognition of People with Stroke
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
History of only one stroke Age range 24 to 65 years Obtaining a minimum score of 60/20 visual acuity on the Snellen chart It has been 1 to 6 months since the stroke. Deficits in visual perception skills using the TVPS test and obtaining a score lower than 85 Ability to follow instructions and complete tests Ability to successfully perform vergence, duction, and near point of convergence (NPC) tests
Exclusion criteria:
History of recurrent strokes and transient ischemic attacks (TIAs) or occurrence of these events during the study Presence of visual impairments due to diabetes, cataracts, etc. Visual field deficit Presence of aphasia and inability to communicate verbally Having serious cardiovascular, respiratory, digestive, etc. diseases. Presence or occurrence of other neurological disorders, psychiatric diseases, serious cardiovascular, respiratory, digestive diseases, etc.
Age
From **24 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
After meeting the study inclusion criteria, stroke patients will be divided into two groups using the random allocation method. The permuted block method will be used for random allocation.
Blinding (investigator's opinion)
Single blinded
Blinding description
The initial and final assessments of participants will be conducted by another occupational therapy master's student who is unaware of the grouping of participants, in accordance with the principles of blinding. For this purpose, coding will be used to identify participants so that the assessor is unaware of the group status. The data analyst will also be unaware of the grouping and will be blinded, in accordance with the principles of data coding.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University o
Street address
school of Rehabilitation, Tehran University of Medical Sciences, pich Shamiran, Corner of Safi Alishah Street, Enghelab Street, Tehran
City
Tehran
Province
Tehran
Postal code
1148965111
Approval date
2025-02-15, 1403/11/27
Ethics committee reference number
IR.TUMS.FNM.REC.1403.193

Health conditions studied

1

Description of health condition studied
stroke
ICD-10 code
164
ICD-10 code description
Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description
OculoMotor score in the OculoMotor Assessment Tool
Timepoint
At the beginning of the study (before the start of the interventions) and at the end of the study (after 10 intervention sessions)
Method of measurement
OculoMotor Assessment Tool (OMAT)

2

Description
Visual Perceptual Skills Score on the Test of Visual Perceptual Skills-3
Timepoint
At the beginning of the study (before the start of the

interventions) and at the end of the study (after 10 intervention sessions)

Method of measurement

Test of Visual Perceptual Skills-3 (TVPS-3)

3

Description

Visual-Motor Integration Score on the Beery-Buktenica Developmental Test of Visual-Motor Integration

Timepoint

At the beginning of the study (before the start of the interventions) and at the end of the study (after 10 intervention sessions)

Method of measurement

Beery-Buktenica Developmental Test of Visual-Motor Integration (Beery VMI-6)

Secondary outcomes

1

Description

Independence in activities of daily living based on the Functional Independence Measure

Timepoint

At the beginning of the study (before the start of the interventions) and at the end of the study (after 10 intervention sessions)

Method of measurement

Functional Independence Measure (FIM)

2

Description

global cognitive function score based on the Mini-Mental State Examination

Timepoint

At the beginning of the study (before the start of the interventions) and at the end of the study (after 10 intervention sessions)

Method of measurement

Mini-Mental State Examination (MMSE)

Intervention groups

1

Description

Intervention group: This group will receive Visual rehabilitation interventions based on Warren's hierarchical model of visual processing (twelve 45-minute therapy sessions, 3 times a week), alongside conventional occupational therapy interventions (twelve 30-minute therapy sessions, 3 times a week). The first and last sessions will be for assessment, and the remaining sessions (10 sessions) will be for implementation of the interventions. Interventions implemented in visual rehabilitation sessions will include: a variety of exercises related to eye movements (saccadic, pursuit, convergent, and divergent movements), visual attention, visual scanning, pattern recognition, visual memory, and visual perception skills (including: visual figure-ground, visual closure, form constancy, spatial relationships, visual sequential memory, and visual discrimination).

Category

Rehabilitation

2

Description

Control group: This group will receive only the conventional occupational therapy interventions (twelve 30-minute therapy sessions, 3 times a week). The first and last sessions will be for assessment, and the remaining sessions (10 sessions) will be for implementation of interventions. Interventions implemented in these sessions will include: preparation of clients, adjustment of muscle tone, balance exercises in sitting and standing positions, mobility exercises, improvement of upper limb function (gross and fine movements), and training in activities of daily living.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Occupational Therapy Clinic, school of Rehabilitation

Full name of responsible person

Mahmoud Mahmoudian

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school of Rehabilitation, Tehran University of Medical Sciences, pich Shamiran, Corner of Safi Alishah Street, Enghelab Street, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Ramin Kordi

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6th Floor, Vice-Presidency for Research and Technology, Central Organization of the Tehran University of medical science, Qods Street Corner, Keshavarz Boulevard

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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Amin MansourLakouraj
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Occupational Therapy
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School of Rehabilitation, Tehran University of Medical Sciences, pich Shamiran, Corner of Safi Alishah Street, Enghelab Street, Tehran
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Person responsible for updating data

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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