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A pilot randomized study comparing non-immersive virtual reality–based upper- and lower-limb rehabilitation plus conventional therapy versus conventional therapy alone in post-stroke patients

Submission date
26/01/2026

Recruitment status
No longer recruiting

Registration date
09/02/2026

Overall study status
Completed

Last Edited
13/02/2026

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Stroke frequently leads to upper- and/or lower-limb impairment, causing weakness and loss of voluntary motor control on one side of the body, which can limit tasks such as reaching, grasping, self-care, walking, standing, and balance. Conventional occupational therapy is effective but can be constrained by limited opportunities for engaging, high-repetition, task-oriented practice. Non-immersive virtual reality rehabilitation, delivered through camera-based motion tracking, provides structured exercise modules for both upper-limb and lower-limb rehabilitation, with real-time visual feedback and gamified tasks that encourage repetition and active participation. The aim of this study is to determine whether adding non-immersive virtual reality–based training to conventional occupational therapy results in greater functional improvement compared with conventional occupational therapy alone.

Who can participate?
Post-stroke patients aged 18 to 80 years with unilateral upper-limb and/or lower-limb weakness

What does the study involve?
Participants are randomly assigned to one of two groups:
1. Conventional occupational therapy alone (control group)
2. Non-immersive virtual reality–based rehabilitation plus conventional occupational therapy (intervention group)
Both groups receive structured rehabilitation sessions for 4 weeks. The virtual reality system uses a camera-based motion tracking method and task-oriented exercise games designed for upper-limb rehabilitation. Upper-limb function is assessed before and after the intervention period using standard clinical assessments of motor function, joint motion, and manual dexterity.

What are the possible benefits and risks of participating?
Participants may benefit from structured upper-limb rehabilitation and may experience improvement in upper-limb movements and function. Risks are minimal and similar to standard therapy, such as muscle fatigue, mild pain, or temporary discomfort. Some participants may experience mild tiredness or frustration during exercise games. All sessions are supervised and rest breaks are provided.

Where is the study run from?
Indian Institute of Technology Madras (India)

When is the study starting and how long is it expected to run for?
September 2023 to July 2024

Who is funding the study?
Indian Institute of Technology Madras (India)

Who is the main contact?
Dr Sourav Rakshit, srakshit@iitm.ac.in

Contact information

Type(s)
Principal investigator

Contact name
Dr Sourav Rakshit

ORCID ID
https://orcid.org/0000-0002-2734-3180

Contact details
Department of Mechanical Engineering
IIT Madras
Chennai
India
600036
+91 (0)6379665494
srakshit@iitm.ac.in

Type(s)
Public, Scientific

Contact name
Mr Sandipan Roy

Contact details
Chalk Kantalia, P.O. Sewli Telini para, North 24 Parganas, West Bengal, Pin
Barrackpore
India

700121
+91 (0)7980965924
me21s078@smail.iitm.ac.in

Additional identifiers

Study information

Scientific Title
A pilot randomized controlled study on the effectiveness of non-immersive virtual reality–based rehabilitation plus conventional occupational therapy versus conventional occupational therapy alone in improving upper- and lower-limb recovery in post-stroke hemiparetic patients

Study objectives
Primary objective:
To evaluate the effectiveness of non-immersive virtual reality–based rehabilitation targeting the upper and/or lower limbs, combined with conventional occupational therapy, compared with conventional occupational therapy alone, in improving functional recovery in post-stroke hemiparetic patients.

Secondary objectives:
1. To compare weekly changes between groups in upper-limb motor function, passive joint motion, and manual dexterity, as well as lower-limb gait, balance, and functional mobility, after the intervention period.
2. To assess the usability and participant acceptability of the non-immersive virtual reality rehabilitation program.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/08/2023, Institutional Research Ethics Board, INK Kolkata (Main Hospital: 185/1 A.J. C. Bose Road Rehabilitation, Research & Psychiatric Centre: 10 West Range, Kolkata, 700017, India; +91 (0)7044060941; ganguly73@gmail.com), ref: N/A

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Upper- and/or lower-limb motor impairment and functional limitation following stroke (post-stroke hemiparesis)

Interventions
Participants are randomized into two parallel groups. The control cohort receives conventional occupational therapy only. The intervention cohort receives non-immersive virtual reality–based rehabilitation targeting the upper and/or lower limbs in addition to conventional occupational therapy. Outcome assessors are blinded to group allocation (single-blinded design), while participant and therapist blinding is not feasible due to the nature of the intervention.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Non-immersive virtual reality based rehabilitation system (camera-based motion tracking exergame platform using a webcam and computer)

Primary outcome(s)
1. Upper limb motor function measured using the Upper Limb Motor Function Test (score /points) at baseline and weekly during the 4-week intervention period, with post-intervention evaluation at Week 4

2. Passive joint motion measured using therapist-assisted passive range of motion assessment (score/points) at baseline and weekly during the 4-week intervention period, with post-intervention evaluation at Week 4

3. Manual dexterity measured using the Box and Block Test (BBT) (number of blocks transferred in 60 seconds) at baseline and weekly during the 4-week intervention period, with post-intervention evaluation at Week 4

4. Cognitive status (screening) measured using the Mini-Mental State Examination (MMSE) (score out of 30) at baseline (Week 0) only

5. Gait speed measured using the 10-Meter Walk Test (10MWT) at baseline and weekly during the 4-week intervention period, with post-intervention evaluation at Week 4

6. Functional mobility measured using the Timed Up and Go (TUG) test at baseline and weekly during the 4-week intervention period, with post-intervention evaluation at Week 4

7. Balance measured using the Berg Balance Scale (BBS) at baseline and weekly during the 4-week intervention period, with post-intervention evaluation at Week 4

8. Dynamic balance and gait measured using the Dynamic Gait Index (DGI) at baseline and weekly during the 4-week intervention period, with post-intervention evaluation at Week 4

Key secondary outcome(s)

Completion date
30/07/2024

Eligibility

Key inclusion criteria
1. Age 18–80 years
2. Unilateral upper-extremity hemiparesis/hemiplegia
3. Medically stable
4. Brunnstrom stage ranging from 2 to 4
5. Modified Ashworth Scale <2
6. Adequate visual acuity (with corrective lenses if needed)
7. No visual neglect, apraxia, or visuospatial perceptual disorders (screened via MMSE visuospatial item and therapist-administered clock-drawing test)

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. History of other neurodegenerative diseases
2. Epilepsy
3. Cardiac pacemaker
4. Severe visual impairment
5. Known case of fracture on the affected side

Date of first enrolment
01/09/2023

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
India

Sponsor information

Organisation
Indian Institute of Technology Madras

ROR
https://ror.org/03v0r5n49

Funder(s)

Funder type

Funder Name
Indian Institute of Technology Madras

Alternative Name(s)
, IIT Madras, IITM

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
India

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available