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# Comparison of clinical outcomes of Virtual Reality assisted rehabilitation with dose-matched conventional rehabilitation in patients with stroke

**Submission date**
14/02/2024

**Recruitment status**
Recruiting

**Registration date**
15/02/2024

**Overall study status**
Ongoing

**Last Edited**
14/02/2024

**Condition category**
Nervous System Diseases

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

## Plain English summary of protocol

Background and study aims
Stroke is the second leading cause of chronic disability and mortality with 102 million disability-adjusted life years lost annually. The majority of stroke survivors are left with some degree of disability, particularly with upper limb dysfunction. Also, innovative methodologies for restorative neurorehabilitation are required to reduce long-term disability and socioeconomic burden. The use of technology-assisted customized strategies can facilitate a faster recovery process.
Our aim is to develop and test a customized Virtual Reality assisted therapeutic protocol that might serve as a relatively more effective treatment plan for the rehabilitation of wrist and finger joints of post-stroke patients.

Who can participate?
Patients aged 18 - 75 years, with stroke having upper-limb disability

What does the study involve?
The study involves giving rehabilitation sessions/interventions (details given in the intervention section) to patients with stroke. Clinical evaluation is done before and after the completion of therapy sessions. Clinical data acquisition includes a battery of clinical scales, functional MRI, cortical excitability measures, task-performance measures, and subjective feedback.

What are the possible benefits and risks of participating?
The information we get from the study will help to improve the post-stroke upper-limb motor function and to increase the understanding of the treatment of stroke. Improvements are expected in upper limb motor function depending upon the size and location of the stroke but might not be directly beneficial to the patients enrolled. No direct risk to patients is involved.

Where is the study run from?
1. All India Institute of Technology, New Delhi, India
2. Indian Institute of Technology Delhi, New Delhi, India

When is the study starting and how long is it expected to run for?
November 2019 to March 2027

Who is funding the study?
Indian Council of Medical Research (ICMR), India

Who is the main contact?
Dr Amit Mehndiratta, amitvmehndiratta@gmail.com

# Contact information

### Type(s)
Public, Scientific, Principal investigator

### Contact name
Dr Amit Mehndiratta

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
55/4/1/CARE-Disability & AT/2020/NCD-II

# Study information

### Scientific Title
CARE-Neuroassistive Technologies for Stroke recovery

### Acronym

CARE-NTS

## Study objectives
Customized Virtual Reality assisted rehabilitation could show higher improvement of distal upper-limb motor function and cortical excitability in patients with stroke as compared to conventional-rehabilitation.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
approved 11/04/2020, Institute Ethics Committee (IEC) (Room no. 2, First floor, Old OT Block, All India Institute of Medical Sciences, Ansari Nagar, New Delhi, 110029, India; +91 11 26594579; ethicscommitteeaiims@gmail.com), ref: IEC-229/11.4.2020

## Study design
Single-center interventional single-blinded randomized controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Recovery of post-stroke motor impairments in response to the Virtual Reality assisted rehabilitation

## Interventions
Randomized: Manually
Duration: 5 days a week for 4 weeks (total 20 sessions)
Given by: Therapist
Settings: Hospital
Time points at which outcome measures taken: At baseline, 4 weeks, 3,6 & 12 months post-therapy
Patients with stroke randomized into 2 groups:
1. Comparator Agent: Physiotherapy - Patient will be asked to do clinical physiotherapy as prescribed by the therapist
2. Intervention: Virtual Reality Assisted Therapy - The patient will be asked to do virtual reality-assisted rehabilitation

## Intervention Type
Device

## Phase
Phase II

## Drug/device/biological/vaccine name(s)
In-house developed Virtual Reality based upper-limb rehabilitation module

## Primary outcome(s)

1. Spasticity is measured using the Modified Ashworth Scale (MAS) at baseline, 4 weeks, 3 months, 6 months and 1 year
2. Motor functionality is measured using Fugl-Meyer Assessment (FMA), Active and Passive Range of Motion (AROM and PROM), Motor Assessment Scale at baseline, 4 weeks, 3 months, 6 months and 1 year
3. Stage of recovery using Bruunstrom Stage (BS) at baseline, 4 weeks, 3 months, 6 months and 1 year
4. Activities of Daily Living (ADL) participation using Modified Barthel Index (MBI) at baseline, 4 weeks, 3 months, 6 months and 1 year
5. Disability level by Modified Rankin Scale (MRS) at baseline, 4 weeks, 3 months, 6 months and 1 year
6. Hand laterality measured by Edinburg scale of laterality index at baseline, 4 weeks, 3 months, 6 months and 1 year
7. Muscle power using Muscle Research Council (MRC) scale at baseline, 4 weeks, 3 months, 6 months and 1 year

### Key secondary outcome(s))
1. TMS Cortical excitability measures i.e., Resting Motor Threshold (RMT), Motor Evoked Potential (MEP), latency at baseline, 4 weeks, 3 months, 6 months and 1 year
2. Functional Neuroimaging (fMRI & DTI) Measures at baseline, 4 weeks, 3 months, 6 months and 1 year.
3. Task-performance measures using time taken to complete, smoothness of trajectory, relative error at baseline and 4 weeks
4. Subjective questionnaire feedback after completion of therapy

### Completion date
30/03/2027

## Eligibility

### Key inclusion criteria
1. Age 18-75 years
2. Gender both male and female
3. Patients with stroke chronicity 3-120 months (The groups in 3month-2 years and 2-10 years will be evaluated post-hoc separately)
4. No previous clinical stroke
5. Single-lesioned, Ischemic / Hemorrhagic Cortical/Sub-cortical stroke type
6. Patient conscious, coherent, comprehendible, cooperative
7. Patient having upper-limb paresis
8. Mini-Mental State Examination (MMSE) score 24-30.
9. MRC power 1-3
10. Modified Ashworth Scale 1, 1+, 2, 3
11. Brunnstrom Stage 3-5
12. EMG activity of EDC muscle present (even if it is a flicker)
13. Surgical intervention to correct hand deformities e.g., tendon transfers with power quantified through surface EMG

### Participant type(s)
Healthy volunteer, Patient

### Healthy volunteers allowed

No

### Age group
Adult

### Lower age limit
18 years

### Upper age limit
75 years

### Sex
All

### Key exclusion criteria
1. Having progressive neurological disorders
2. Cognitively declining (MMSE < 24)
3. Clinically unstable
4. Contraindications to MRI and TMS procedure
5. Having Aphasia
6. Major stroke (NIHSS >16)

### Date of first enrolment
12/05/2020

### Date of final enrolment
01/03/2027

## Locations

### Countries of recruitment
India

### Study participating centre
**All India Institute of Medical Sciences New Delhi**
Ansari Nagar, South west Delhi
New Delhi
India
110029

### Study participating centre
**Indian Institute of Technology Delhi**
Hauz Khas
New Delhi
India
110016

# Sponsor information

**Organisation**
Indian Council of Medical Research

**ROR**
https://ror.org/0492wrx28

# Funder(s)

**Funder type**
Government

**Funder Name**
Indian Council of Medical Research

**Alternative Name(s)**
Indian Council of Medical Research, Government of India, Indian Council of Medical Research (ICMR), New Delhi, ICMROrganisation, , Indian Council of Medical Research, New Delhi, . . . ., ICMR, ICMRDELHI, ...

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
India

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated and/or analyzed during the current study will be available upon request from the PI (Dr Amit Mehndiratta, amitvmehndiratta@gmail.com).

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |