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# Robotic hand therapy for rehabilitation after brain damage caused by stroke

**Submission date**
07/11/2024

**Recruitment status**
Recruiting

**Registration date**
08/11/2024

**Overall study status**
Ongoing

**Last Edited**
08/11/2024

**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 was to develop and test a customized Robotic Exoskeleton to assist flexion and extension of wrist and fingers in a way to improve Activities of Daily Living as assistive technology for a therapeutic benefit that might serve as a relatively more effective and tailored treatment plan for the rehabilitation of wrist and finger joints of post-stroke patients.

Who can participate?
Patients aged 18 - 70 years, with stroke or paralysis.

What does the study involve?
The study involves giving therapy 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 functional MRI, clinical scales, cortical excitability 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 functioning of the hand with stroke and to increase the understanding of the treatment of stroke. Improvements are expected in upper limb movement and 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. Indian Institute of Technology, Delhi, India
2. All India Institute of Technology, New Delhi, India
3. Paras Hospital, Gurugram, Haryana, India

When is the study starting and how long is it expected to run for?
April 2020 to March 2028

Who is funding the study?
Indian Council of Medical Research (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

### 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-Robotic

### Study objectives
Robotic-hand exoskeleton-assisted rehabilitation could show higher improvement of distal upper-limb motor function in patients with stroke as compared to conventional rehabilitation.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
1. 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

2. Approved 04/10/2024, Paras Hospital, Gurugram (C-1 Sushant Lok- 1 Sector-43 Phase- I, Gurgaon, Haryana, 122002, India; +91 9891418288; narender.s@parashospitals.com), ref: PHPL /PHIEC-COMM/2024/012

## Primary study design
Interventional

## Study design
Multi-centric interventional single-blinded randomized controlled trial

## Study type(s)
Treatment

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

## Interventions
Randomized: Manually
Duration: 5 days a week for 4 weeks (total 20 sessions)
Given by: Therapist at clinic and caregiver at home
Settings: Hospital / Home
Time points at which outcome measures taken: At baseline, 4 weeks, 3, 6 & 12 months post-therapy
Patients with stroke randomized into 3 groups:
1. Comparator Agent: Physiotherapy - The patient will be asked to do clinical physiotherapy as prescribed by the therapist
2. Intervention one: Robotic hand Assisted Therapy at clinic - The patient will be asked to do Robotic hand assisted rehabilitation
3. Intervention two: Robotic hand Assisted Therapy at Home - The patient will be asked to do Robotic hand-assisted rehabilitation at home with the help of a caregiver. Caregiver and patient will be trained before the start of therapy.

## Intervention Type
Device

## Phase
Phase III

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

## 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
8. Modified Barthel index (mBI) t baseline, 4 weeks, 3 months, 6 months and 1 year
9. Stroke Impact Scale (SIS) at baseline, 4 weeks, 3 months, 6 months and 1 year
10. Motor Activity LOG (MAL) at baseline, 4 weeks, 3 months, 6 months and 1 year
11. Action Research Arm Test (ARAT) 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 five different time points
2. Functional Neuroimaging (fMRI & DTI) Measures at five different time points
3. Electromyography (EMG) at five different time points
4. Motor Assessment Scale (MoAS) at five different time points
5. Subjective questionnaire feedback after completion of therapy after the completion of the therapy sessions
6. System Usability scale after the completion of the therapy sessions

### Completion date
30/03/2028

## 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 3 month-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 flexor and extensor compartment of forearm 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
01/04/2023

### Date of final enrolment
30/03/2027

## 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**
**Paras Hospital, Gurugram**
C-1 Sushant Lok- 1 Sector-43 Phase- I
Gurgaon, Haryana
India
122002

**Study participating centre**
**Indian Institute of Technology, Delhi**
IIT Campus, Hauz Khas, Delhi
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
All data generated or analyzed during this study will be included in the subsequent results publication.

### IPD sharing plan summary
Published as a supplement to the results publication