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Robotic hand therapy for rehabilitation after brain damage caused by stroke

Submission date 07/11/2024	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 08/11/2024	**Overall study status** Ongoing	
Last Edited 08/11/2024	**Condition category** Nervous System Diseases	

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

ORCID ID
http://orcid.org/0000-0001-6477-2462

Contact details
Centre for Biomedical Engineering, Indian Institute of Technology
New-Delhi
India
110016
+91-11-2659-6230
amehndiratta@cbme.iitd.ac.in

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Pharmaceutical study type(s)
Not Applicable

Phase
Phase III

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

Primary outcome measure
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

Secondary outcome measures
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

Overall study start date

11/04/2020

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
200

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

Sponsor details
V. Ramalingaswami Bhawan, P.O. Box No. 4911Ansari Nagar
New Delhi
India

110029
+91-11-26594579
icmrhqds@sansad.nic.in

Sponsor type
Government

Website
http://www.icmr.nic.in/

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

Publication and dissemination plan
Planned publication in a high-impact journal.

Intention to publish date
01/01/2026

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