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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

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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

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

Secondary study design
Randomised controlled trial

Study setting(s)
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 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

Pharmaceutical study type(s)
Not Applicable

Phase
Phase II

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

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

Secondary outcome measures
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

Overall study start date
20/11/2019

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
100

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

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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 peer-reviewed journal

Intention to publish date
30/03/2028

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