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COMPARATIVE STUDY OF HAPTIC-AUGMENTED ROBOTIC TRAINING, ROBOTIC TRAINING, AND CONVENTIONAL THERAPY ON UPPER-LIMB MOTOR RECOVERY AFTER STROKE: A THREE- ARM RANDOMIZED CONTROLLED TRIAL PROTOCOL

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Abstract:

Introduction: Upper-limb motor impairment is a common consequence of stroke that significantly affects hand function, dexterity, and independence in daily activities. Conventional physiotherapy remains a key component of rehabilitation; however, it may not always provide sufficient intensity, repetition, or sensory feedback to optimize motor recovery. Robotic-assisted therapy enables repetitive, task-specific training, while haptic feedback may enhance sensorimotor integration and cortical reorganization through augmented tactile input.

Need for the Study: Stroke is a leading cause of long-term disability worldwide, and upper-limb dysfunction greatly impacts quality of life. Although robotic-assisted rehabilitation has shown promise in improving motor recovery, evidence comparing haptic-augmented robotic training, robotic training alone, and conventional physiotherapy remains limited. Establishing the most effective intervention could improve rehabilitation outcomes and guide clinical practice.

Aim: To compare the effects of haptic-augmented robotic training, robotic training alone, and conventional physiotherapy on upper-limb motor recovery in individuals with subacute stroke.

Materials and Methods: A single-blinded, three-arm parallel-group randomized controlled trial will be conducted on 45 participants with subacute stroke recruited from the Neuro-Physiotherapy OPD and IPD of MGM Medical College and Hospital. Participants will be randomly allocated to Haptic-Augmented Robotic Training (HART), Robotic Training (RT), or Conventional Physiotherapy groups. Each group will receive 60-minute sessions, five days per week for four weeks. Outcomes will be assessed using the Fugl-Meyer Assessment-Upper Extremity (FMA-UE), Jebsen-Taylor Hand Function Test (JTHFT), and Functional Independence Measure (FIM) at baseline and post-intervention.

Conclusion: Haptic-augmented robotic training is hypothesized to produce superior improvements in motor recovery, hand function, and functional independence compared to robotic training alone and conventional physiotherapy.

Index Terms– Subacute Stroke, Upper-limb Rehabilitation, Haptic-Augmented Robotic Training, Robotic Therapy, Motor Recovery, Conventional Physiotherapy, Hand Function.

I. INTRODUCTION

Stroke is defined as evidence of focal ischemic injury in a blood vessel area, whether through imaging, objective findings, or clinical symptoms that last more than 24 hours or until death, as long as other causes are ruled out.[1] It is a leading cause of disability worldwide. Many people lose their independence and experience a lower quality of life.[1] Despite improvements like stroke units, thrombolysis, and thrombectomy, many survivors still face lasting impairments.[2] This highlights the need for rehabilitation approaches based on neuroplasticity. These approaches include cortical remapping, synaptic reorganization, and motor relearning to aid recovery and enhance the quality of life.

In India, stroke ranks as the fourth leading cause of death and the fifth cause of disability. The incidence ranges from 108 to 172 per 100,000, while prevalence varies between 26 and 757 per 100,000. One-month fatality rates are high, between 18% and 42%. The average age of stroke onset 62.2 years, which is younger than the global average, and nearly one-fifth of cases involve individuals under 40. [3] These trends underline the urgent need for prevention, monitoring and fair access to care.

Upper-limb impairment is among the most common and disabling outcomes, affecting about 80% of survivors initially. Although some recovery is possible, nearly half of those affected remain functionally limited in the long run. Complications such as weakness, sensory loss, spasticity (20% to 40% within a year), abnormal movement patterns and pain further impede recovery.[4] These challenges call for targeted interventions.

Robotic-assisted rehabilitation provides high doses of repetition and engaging motor training, thereby easing the burden on therapists.[5] This method addresses the shortcomings of traditional therapy. However, many systems do not incorporate somatosensory feedback, which is crucial for motor control and neuroplasticity. Since over half of the stroke survivors experience sensory deficits, adding sensorimotor feedback is vital.[6]

Haptic technology offers detailed feedback during robotic-assisted tasks, improving ecological validity, supporting cortical reorganization, and facilitating skill transfer. Integrating this technology into robotic rehabilitation is a significant step toward restoring upper-limb function and independence.

II.MATERIALS AND METHODS

Study Design

A single-blinded, three-arm parallel-group Randomized Controlled Trial (RCT) will be conducted to compare the effects of Haptic-Augmented Robotic Training (HART), Robotic Training (RT), and Conventional Physiotherapy on upper-limb recovery in individuals with subacute stroke.

Study Setting

Participants will be recruited from the Neuro-Physiotherapy Outpatient Department and Inpatient Department of MGM Medical College and Hospital. Ethical clearance was obtained from the Institutional Ethics Committee (MGM-ECRHS/2026/28) prior to commencement of the study, and written informed consent will be obtained from all participants.

Study Duration

The total study duration will be 1 year. Each participant will undergo a 4-week intervention period.

Sample Size

Sample size estimation was performed using G*Power software (F tests – ANOVA: Fixed effects, special, main effects, and interactions). An a priori power analysis was conducted with the following parameters: effect size (f) = 0.4858658, alpha (α) = 0.05, power (1–β) = 0.80, numerator degrees of freedom (df) = 2, and number of groups = 3.

The analysis yielded a required total sample size of 45 participants (denominator df = 41; critical F = 3.2256838; noncentrality parameter λ = 10.3868853), achieving an actual power of 0.8004907. Participants were equally allocated into three groups.

Sampling Method and Randomization

Participants will be recruited using consecutive sampling. After baseline assessment, participants will be randomly allocated into one of three groups:

1. **Group A:** Haptic-Augmented Robotic Training
2. **Group B:** Robotic Training
3. **Group C:** Conventional Physiotherapy

Randomization will be performed using sequentially numbered opaque envelopes prepared by an independent investigator. Outcome assessors will remain blinded to group allocation.

ELIGIBILITY CRITERIA

Inclusion Criteria

1. Individuals diagnosed with stroke within the past 6 months (subacute stage).
2. Age between 55–75 years.
3. Either gender.
4. MoCA score greater than 24.
5. Brunnstrom recovery stage III–V for upper extremity.
6. Presence of minimal voluntary movement of wrist or fingers
7. Spasticity < 3 on Modified Ashworth Scale at wrist and finger joints.
8. Ability to follow commands and provide informed consent.

Exclusion Criteria

1. Unstable vital signs.
2. Irreversible contracture of the affected upper-limb.
3. History of upper-limb fracture, arthritis, or chronic pain limiting function.
4. Uncontrolled post-stroke seizures.
5. Myocardial infarction or major cardiovascular event within the past 3 months.
6. Recent upper-limb surgery or implanted medical devices.
7. Participation in another experimental rehabilitation trial within the past 3 months.

INTERVENTION PROTOCOL

All groups will receive equal intervention duration of 60 minutes/day, 5 days/week, for 4 weeks.

Group A: Haptic-Augmented Robotic Training (HART)

Each session will consist of 30 minutes of structured haptic sensory discrimination training followed by 30 minutes of robotic-assisted upper-limb training. The haptic training will use standardized objects varying in texture, shape, size, weight, hardness, and contour.

Group B: Robotic Training (RT)

Each session will consist of 60 minutes of robotic-assisted upper-limb training with standardized progression criteria.

Group C: Conventional Physiotherapy

Each session will consist of 60 minutes of conventional physiotherapy including stretching, tone normalization, strengthening, and task-oriented upper-limb training

GROUP A: HAPTIC-AUGMENTED ROBOTIC TRAINING	GROUP B: ROBOTIC TRAINING	GROUP C: CONVENTIONAL PHYSIOTHERAPY
• 60 standardized objects varying in texture, shape, size, weight, hardness, and contour • Warm-up trials-structured object exploration, matching, and discrimination tasks • Active assisted movement of MCP, DIP, PIP, CMC, IP and wrist flexion/extension	• Active assisted movement of MCP, DIP, PIP, CMC, IP and wrist flexion/extension • Gradual reduction in robotic assistance as voluntary control improves • Progression to grasp/release tasks: cylindrical, spherical, lateral pinch)	• Stretching of tight muscles • Tone normalization using Rood's approach • Strengthening of weak muscles • Task-oriented upper-limb training

III.OUTCOME MEASURES

Primary Outcome Measures

Fugl-Meyer Assessment for Upper Extremity (FMA-UE): This stroke-specific, performance-based scale is used to assess motor impairment of the upper-limb. It evaluates movement patterns, reflex activity, coordination, and joint functioning, with higher scores indicating better recovery.

Secondary Outcome Measure

Jebsen–Taylor Hand Function Test (JTHFT): This test measures functional hand performance through timed tasks that simulate activities of daily living.

Functional Independence Measure (FIM): The FIM is a standardized tool used to assess the level of disability and the amount of assistance required for activities of daily living.

IV.STATISTICAL ANALYSIS

Descriptive statistics will be used to summarise demographic and baseline variables. A two-way repeated measures ANOVA will be used to analyse interaction effects between time and group. Post-hoc Bonferroni correction will be applied where appropriate. Statistical significance will be set at $p<0.05$.

V.DISCUSSION:

This protocol introduces a three-arm design that isolates the contribution of haptic feedback by comparing Haptic-Augmented Robotic Training (HART) against Robotic Training (RT) alone and Conventional Physiotherapy. This approach directly addresses a gap identified by Ratz et al., who observed that "most current systems lack the provision of somatosensory information that is congruent with the virtual training task" and that existing devices still tend to be "highly complex and/or bulky, hampering their potential clinical applicability".[10] Li et al., similarly noted that "most hand rehabilitation robots commonly applied in clinics are based on a passive training mode and lack the sensory feedback function of fingers" adding that while force feedback robots "can compensate for these effects," their clinical efficacy remains uncertain.[11] By structuring HART as 30 minutes of structured haptic sensory discrimination using 60 standardized objects varying in texture, shape, size, weight, hardness, and contour followed by 30 minutes of robotic-assisted training, our protocol provides a clear contrast arm (RT without haptics) that isolates the sensory-augmentation effect from the motor-repetition effect. This disentanglement is absent from prior two-arm comparisons and directly answers the question of whether sensorimotor integration confers an additional benefit over robotic motor training alone.

Our primary and secondary outcome measures reflect both the strengths and the identified gaps of prior work. Ratz et al., explicitly acknowledged as a limitation that their usability study lacked" standardized assessment of the participant's sensorimotor ability (e.g., Fugl-Meyer, Barthel-Index, or Box and Block test).[10] Our protocol corrects this by employing the Fugl-Meyer Assessment for Upper Extremity (FMA-UE) as the primary outcome, supplemented by the Jebsen-Taylor Hand Function Test (JTHFT) for the hand dexterity and the Functional Independence Measure (FIM) for activities of daily living.

Li et al., who found significant between-group differences on FMA-Hand and ARAT in favour of their force-feedback robot group, similarly noted that their ADL measure (Barthel Index) "tends to determine whether patients can complete activities of daily living but does not provide detailed requirements on the degree of participation of the affected hand" a limitation our use of the FIM and JTHFT is designed to address.[11]

The therapist and patient perspectives captured by Ratz et al. reinforce the rationale for structured haptic discrimination training. One therapist in their study stated that "the (sensory) input is more important and makes it more real. It's important from a therapeutic point of view because it's more comparable to everyday life" while a patient noted that the interaction was a natural interaction. There was a realistic feeling. I felt that I was grasping something. The therapists further expressed "confidence in the transferability of sensorimotor skills learned with our system to activities of daily living, although further investigation is needed to confirm this". Our protocol's use of 60 everyday objects varying across multiple sensory dimensions during the haptic discrimination phase directly operationalises this ecologically valid sensory training, moving beyond the single-device haptic rendering tested by Ratz et al. toward a scalable, low-cost sensory stimulation protocol that can be delivered alongside robotic training.

Ranzani et al., observed that "there is evidence that increasing therapy dose after stroke might promote recovery. Unfortunately, in clinical practice, therapy dose is limited by financial and organizational constraints" and that "simple robotic devices could be used without supervision in the clinic or at home to increase dose without requiring additional resources".[13] They further noted that "the use of robotic devices is currently mainly limited to short therapy sessions in the clinics under constant supervision of specialized therapists, which limits their potential as a vector to increase therapy dose".

In summary, this three-arm RCT protocol fills a well-documented gap in the literature by: (i) isolating haptic sensory augmentation as the independent variable through a three-arm comparison; (ii) enrolling a homogenous subacute stroke population to reduce heterogeneity; (iii) employing standardized, validated outcome measures that prior studies omitted or found inadequate; and (iv) deriving its sample size from a priori power analysis that meets the methodological standards called for by recent meta-analyses.[12] The results will provide the level of evidence needed to determine whether adding structured haptic sensory discrimination to robotic motor training may produce clinically meaningful gains over robotic training alone and over conventional physiotherapy in subacute stroke survivors.

VI.CONCLUSION:

In summary, this three-arm RCT protocol fills a well-documented gap in the literature by: (i) isolating haptic sensory augmentation as the independent variable through a three-arm comparison; (ii) enrolling a homogeneous subacute stroke population to reduce heterogeneity; (iii) employing standardized, validated outcome measures that prior studies omitted or found inadequate; and (iv) deriving its sample size from a priori power analysis that meets the methodological standards called for by recent meta-analyses.
The results will provide the level of evidence needed to determine whether adding structured haptic sensory discrimination to robotic motor training produces clinically meaningful gains over robotic training alone and over conventional physiotherapy in subacute stroke survivors.

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