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Original Article

Synergy-based motor therapy for post-stroke hemiparetic subjects: A randomized controlled trial

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ABSTRACT

Objectives: Motor recovery is inclusively based on the severity of abnormal coupling or the abnormal synergistic actions among the post-stroke hemiparetic subjects. The normal synergistic pattern shall be incorporated to inhibit the abnormal synergistic behavior to attain motor control.

Materials and Methods: A randomized controlled double blinded (assessor and subjects) trial was conducted in a rehabilitation institute. One hundred and thirty-six post-stroke (mean duration, 12.73 ± 9.52 months) hemiparetic subjects were conveniently selected and randomly allocated in two groups (experimental, 68 and control, 68). The experimental group received synergistic-based motor therapy (SBMT) protocol and the control group of the subjects received the conventional occupational therapy intervention. Both of the groups received dose-matched intervention for the period of 3 months, 48 sessions (4/week). Normal synergistic linkage was being exploited to encounter the abnormal synergistic patterns. The main outcome measures were Fugl-Meyer Assessment - upper extremity (FMA-UE), arm (FMA-A), wrist-hand (FMA-WH) for the motor recovery and Finger Breadth Palpation method (FBP) for the shoulder subluxation.

Results: In comparison to the control group, the experimental group exhibited highly significant results. The mean score of FMA-UE was changed to 41.32 ± 11.50 from the pre-intervention score of 25.76 \pm 15.26 (P < 0.001). Post-intervention, the mean score of FMA-A was increased to 26.89 \pm 0.93 from 17.36 \pm 1.21 (P < 0.001). The pre-assessment score of FMA-WH was 8.29 \pm 0.96 and post-intervention, it was increased to 14.13 \pm 0.88 (P < 0.001). The experimental group of subjects was recorded to have a reduction in the shoulder subluxation. The grade of FBP reduced to 0.39 ± 0.11 from the pre-intervention score of 1.23 \pm 0.13 (P < 0.001).

Conclusion: SBMT was concluded to be superior and highly significant than the conventional intervention for enhancing upper limb motor recovery among post-stroke hemiparetic subjects. Further, the grade of shoulder subluxation was also found to be significantly reduced among the SBMT group participants in comparison to the control subjects.

Keywords: Fugl-Meyer assessment, Hemiparesis, Motor deficits, Motor functions, Motor recovery, Shoulder pain

INTRODUCTION

The post-stroke subjects present with a diverse range of impairments and hence with varied disability. [1,2] Abnormal motor presentation of the upper limb is most pronounced and challenging in comparison to other impairments. In addition, the extraordinarily complex inter-limb and intra-limb motor demands for the various functions might add to such observations.[3]

Upper limb functions are the outcome of synergistically linked movements among healthy subjects. [4,5] The same is being referred to as "muscle synergy" in the literature with varied theories and definitions.^[6]

Such muscle synergy mechanisms and synchronization get hampered after a stroke. It appears in the shape of loss of independent joint control and is being referred to as "abnormal muscle synergy." [7] The role of muscle synergy is also considered as an indicator of the motor recovery process among stroke subjects.[8] The recovery begins from no movement to the stereotyped synergy pattern and after achieving the individual joint control the subject can be ranked as near to normal stage. [9,10] In addition to this, muscle synergy can facilitate and inhibit motor recovery in post-stroke hemiparesis.[11-15]

Signe Brunnstrom elaborated flexor and extensor synergies for both the upper and lower limbs among hemiparetic

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subjects. For years, the concept has been assessed, analyzed, and intervened in parts or individual movements. It is evident that flexor synergy is more pronounced in the upper limb and encompasses the great challenges to reduce its effect. The synergistic pattern is found to be responsible for the abnormal coupling of shoulder movements with distal hand functions. [16]

To our knowledge, none of the studies supports the single-comprehensive motor intervention for post-stroke upper limbs. The advancement, refinement, and development of intervention protocols are an ongoing process. Hence, it will be wise to develop a protocol utilizing the motor control principles that may be applicable throughout the motor recovery stages of the arm and hand.

Stage-wise motor rehabilitation utilizing the synergistic linkage is still unexplored. Various synergistic components have been studied and proved to significantly related with the motor recovery.[17]

The present study is a step to develop a synergy-based motor intervention that would be applicable throughout the various recovery stages. Further, the objective of the study was to determine the effectiveness of synergy-based motor therapy (SBMT) on the motor recovery of the upper limb, function, and disability status.

MATERIALS AND METHODS

The data were collected from October 2023 to September 2024. The study is based on the PhD thesis work of the first author. The CONSORT guidelines were followed for reporting the present study.

Aim of the study

Based on the findings of "Synergy-Based Motor Therapy Inducing Favorable Changes Motor Function Components among Post-stroke Subjects: A Single-Group Study,"[18] This Randomized Controlled Trial (RCT) is being conducted.

Design

A randomized controlled, double-blinded trial.

Setting

Rehabilitation Institute.

Ethical approval

The study was approved by the Institutional Ethical Committee of PDUNIPPD, New Delhi (Approval number Code No.: IEC13/2023/RP1) and Ethical Committee of Santosh Deemed to be University (Approval number: SU/2023/068/,^[7] Ghaziabad, Uttar Pradesh.

Trial registration

The study was registered under the Clinical Trial Registry of India Registration number: (CTRI/2023/10/058803).

Sample size calculation

Based on the findings (change in FMA-UE) of the previous work, [18] the sample size was estimated using the value of mean change of 8.9, standard deviation (SD) = 17.64, and beta = 80%. Accordingly, 62 subjects were recruited in each group to discern the desired change. In view of 10% dropouts, a total of 136 subjects were enrolled. The stroke subjects were randomly divided into the experimental and the control groups of intervention.

Participants

A total of 209 post-stroke subjects reported to the study site (PDUNIPPD) were screened, out of which 136 subjects were conveniently selected considering the inclusion criteria.

Recruitment and randomization

The study period, protocol, and assessment procedure were explained to each subject in their local language. The subjects were enrolled after receiving the written informed consent by the subject and the first family member prior to the study. The subjects were randomly divided into experimental or control groups. The randomization was performed by using the computer-generated random numbers. The blocks were numbered and a random number generator program was used to select numbers that found the series in which the subjects were being assigned to either one or the other group. The allocated intervention was enclosed in a sealed envelope and was kept with the colleague, who was not aware of the study protocol. It was a double-blinded study, the assessor and the subjects were not aware of which subject was being allocated in which group.

Subjects were included, if they had (1) non-traumatic stroke; (2) either ischemic or hemorrhagic stroke; (3) either right or left hemiparetic; (4) up to 3 years of onset; (5) age 20-75 years; (6) with or without shoulder subluxation. Subjects were excluded from the study if they exhibited (1) severe communication deficits; (2) severe contracture of arm and hand; (3) severe cognitive and perceptual deficits; (4) cardiovascular instability; (5) uncontrolled medical illness; (6) any other musculoskeletal disorder.

Dosage

Forty-eight intervention sessions (4/week) were provided during the period of three months. Dose-match control intervention was provided to the control group of subjects. The duration of the first 24 sessions was 60 min and incrementally graded to 90 min for the next 24 sessions. Pre and post-assessment was done utilizing the following outcome measures. One-month follow-up was done to assess the retention of the intervention protocol.

Outcome measures

Fugl-Meyer assessment (FMA)

FMA is the most widely used stroke-specific tool to assess motor recovery. [9,16-19] The scale exclusively covers the motor components of the FMA-upper arm (FMA-UA), FMA-wrist and hand (FMA-WH) separately and the same can be summarized to observe the recovery of the whole FMA-upper extremity (FMA-UE). It is a performance-based scale and it can be applied as per the evident instructions by the author.[19] There are 33 motor components for the upper limb and they are hierarchically organized from synergistic movement pattern to voluntary motor control of the upper limb. Each of the components scores from 0 (no performance), 1 (initiation or some amount of movement), and 2 (faultless performance). The total points for the upper extremity section of FMA-UE are 66, with a sub-score of 36 for the FMA-UA and 30 for the FMA-WH.

Brunnstrom recovery stage (BRS)

The recovery of BRA-arm (BRS-A) and BRA-hand (BRS-H) is separately classified and categorized into six motor stages. The stages range from no voluntary movement (stage-1) to isolated voluntary movement (stage-6), and the stage is also mentioned as a near-to-normal stage. Each higher stage indicates positive motor recovery. The stage progresses from flaccid tone to increased muscle tone till severe or peak of the spasticity and as the recovery inclines the tone keeps on declining. Finally, both the tone and the voluntary movement appear near to normal. BRS was found to be a valid and responsive tool for assessing the recovery.[20,21]

Finger breadth palpation method (FBP)

The author recommended placing the index finger to palpate the space between the acromion process of the scapula and the head of the humerus to assess shoulder subluxation. The subluxation is graded at three levels - 1: minimal (finger partially inserted); 2: moderate (finger completely inserted); or 3: severe (space available after inserting the finger). The assessment technique has been found to be a reliable and valid measure.[22] Further, the method has been found to be used in stroke-related studies.[23]

Barthel index (BI)

The scale is known to measure the functional status of the subjects. It is a 10-item scale used to measure independency in activities of daily living (ADL). Each subtest item is rated 0, 5, or 10 (or 15 for two of the test items), with a maximum total score of 100. The 10-item interview-based BI measures a person's daily functioning specifically self-care and mobility activities (feeding, mobility, transfer, bathing, dressing, and toileting). The subject receives a score based on whether assistance is required during the performance. The scale has been widely used for stroke subjects and has high reliability and validity as well as moderate responsiveness to changes in functional ability over time.[24]

Modified Rankin scale (mRS)

It is a clinician-reported measure of global disability. mRS measures the degree of disability or dependence in daily activities, ranging from no symptom to severe disability. It is widely used to assess the disability status among stroke subjects. [21] The mRS scores from 0 (no symptoms at all) to 5 (severe disability).

Interventions

The experimental group of subjects received the stage-wise SBMT protocol^[18] and the control group of subjects received the conventional occupational therapy. Few need-based modifications were made in the experimental protocol of the present study. For instance, for acute and sub-acute stroke, subjects with post-stroke shoulder subluxation, and BRS-1 were also enrolled contrary to the previous one, which was a feasibility study. The feasibility study of this protocol was found to be safe; hence, shoulder subluxation of any of the grades was also being enrolled and allocated in either of the groups. Evident shoulder support was provided for both groups of subjects, and the pain and discomfort were considered during the intervention. Evident-based precautions were being followed during both the protocols. Subjects with Stage-1 of BRS-A were also enrolled, and the evident experimental protocol was added with the following movements-

- Scapular elevation was provoked by providing resistive scapular elevation on the less-affected side. Subjects were made to sit in an erect sitting position and resistance was being provided the scapular elevation with the weighted cuff placed at the scapular level. The amount of the weight (250 g, 500 g, 750 g) was being decided as per the reflex response for initiation of scapular elevation on the affected side.
- Scapular protraction-retraction was provided with the bilateral sanding block at the horizontal sanding table. Erect sitting on the armless chair and instruct the subject to keep the arm at 90° on the table. Bilateral protraction and retraction were performed maintaining the elbow straight. A strap was tied at the thoracic level 12 to avoid forward bending as a compensatory movement. The

- therapist will hold the upper and medial border of the scapula to palpate the amount of scapular elevation.
- 3. The subject was in an erect supine position and resistance was being provided on the lateral border of the arm to perform abduction on the less-affected side, and initiation of abductor activity was being observed on the affected side.

Control intervention

The control intervention was provided in the form of a conventional occupational therapy program, based on the neurophysiological principles. [25,26] The concept is based on the neural plasticity responsible for the adaptation and reorganization of brain structures. Repeated stimulation of the brain can lead to a non-involved part of the brain, functionally compensating for the involved parts. The neurophysiological approaches "Adult Hemiplegia by Berta Bobath"[27] and "Brunnstrom Movement Therapy for Hemiplegia"[9] by Sawner were utilized for the control intervention. A structured, stage-specific, and dose-matched intervention program was provided to the control group of subjects.

Bobath intervention program

The concept of Bobath is based on neurophysiological principles; hence, the author termed the technique as Neurodevelopmental Technique. [27] The approach has been applied to the stroke subjects and concluded to achieve favorable results.^[28] Basically, two assumptions were being utilized by the author in this technique. First, it was mentioned that reflexes are the basic units of motor control, and second, the motor control is hierarchically arranged. Although the principles and techniques are being applied in regular clinical practice, the evidence is sparse and found to be utilized in parts. The author recommended implementing this technique as the muscle tone alters, as elaborated-

- 1. Initial flaccid stage Sudden loss of movement, appears as a stage of flaccidity or no tone immediately after the onset of stroke. At this stage, bed positioning of the affected side including the arm and trunk is of utmost importance. Bed mobility was trained incorporating arm movements. The subject was to auto-clasp both hands, elevate the arms at 90°, maintain the elbow straight, and perform the trunk activity. After achieving this, supine to side lying and then coming in the sitting position was being trained for both sides alternatively.^[27]
- Stage of spasticity Middle stage is known as the spastic stage, tone insidiously get changes from flaccidity to spasticity. Patterns of spasticity are flexors in the upper limb and extensors in the lower limb. The elbow and wrist are the main joints to have severe spasticity. Arm weight bearing in sitting followed by standing position,

- pushing the wall was being incorporated to facilitate extensor activity of the arm and to inhibit flexor tone. The arm was trained in relation to the shoulder girdle in supine, side-lying followed by sitting. Erect sitting and standing followed by sit-to-stand were being trained at
- Stage of relative recovery This stage is considered to be the higher stage of relative recovery. Spasticity continues to reduce and motor control of the arm appears to be improved. The arm was being trained to hold against gravity in various functional positions. Incrementally, the range of the arm was being held horizontally to achieve horizontal abduction.^[28] The same were incorporated to utilize the arm and hand movements in all functional activities. The technique was concluded to be equally beneficial for various motor functions when it was compared with constraint-induced movement therapy (CIMT).[29]

Brunnstrom movement therapy

This approach is based on the sequential pattern of motor recovery among post-stroke hemiparesis. The technique emphasizes the synergistic pattern of movement that develops during the recovery process. At BRS-1 and 2, being a flaccid stage, there is no or slight initiation of movement at this stage. Since there is no movement and no tone at this stage, it is considered to be the most vulnerable stage for the shoulder joint. At BRS-3, the synergistic abnormal motor presentation makes its existence, and spasticity increases at its maximal level. At this stage, strong components of both the flexor and extensor synergy appear and get abnormally coupled. This is considered to be the most challenging stage in reference to the motor recovery process. The duration of this stage depends upon various good and bad prognostic signs. Due to its prolonged duration, functional use of basic limb synergies was being incorporated followed by the variations in movement directions. At BRS-4 movements out of synergy, for instance, placing the hand behind the body, elevation of the arm to a sideward-horizontal position, and pronation-supination with the elbow at 90° were provided. BRS-5 is considered to be the higher or good recovery stage. As the out-of-synergy movements make their appearance, tonal influence reduces to a minimal level. BRS-6 is mentioned as the stage of near to normal movements, very negligible subjects reach this stage. This is the only technique that divides the whole recovery process into six hierarchical motor recovery stages. [9] There is sparse evidence to support the intervention technique. However, multiple authors studying the techniques from older to advanced utilize the synergistic linkage. Strong and weak components have been mentioned, utilized, and studied by various authors in various techniques.[13,30]

The technique was found to be superior to motor relearning program (MRP) for the motor recovery of the hand among stroke subjects.[31]

Statistical analysis

Data were collected using the clinical methods as abovementioned outcome measures and the same was entered in an MS Excel spreadsheet and analyzed using the IBM Statistical Package for the Social Sciences-23. Chi-square was applied to examine the demographic and baseline characteristics of the two groups. The missing data for the post-intervention assessments were considered by carrying forward the pre-intervention scores. Accordingly, the intention-to-treat analysis was utilized. The mean (SD) was reported for the continuous data of all the outcome measures. Further, parametrically, the analysis of variance (within factor, time and between factor, group, df = 1) was used to analyze the difference in post-intervention scores between the two groups. The P < 0.05 was considered as significant. 95% confidence interval for the mean difference (pre- and post-intervention) of each outcome measure was also analyzed. Bonferroni correction was executed in case of significant findings to reduce the probability of type 1 error.

RESULTS

A total of 136 post-stroke subjects were enrolled for the present study. Five and eight subjects, respectively, in the experimental and control groups were lost for the post-assessment. No adverse events were reported after the intervention. 89 (65.44%) were male and 47 (34.55%) were female subjects. The mean age of the enrolled population was 51.07 ± 14.41 years. The mean duration of the post-stroke was recorded to be 12.73 ± 9.52 months. There were 120 (88%) subjects with ischemic stroke and the remaining 16 (12%) were hemorrhagic stroke. Among the total enrolled subjects, 73 (55%) were right hemiparetic, and 63 (45%) were left hemiparetic. Right-handed subjects were

132 (97%) and the remaining 4 (3%) were left-handed. As per the occupational activity of the enrolled subjects, only 20 (15%) were continuing with the same occupation, the remaining 3 (5%) changed their occupation, and 113 (80%) subjects were not doing anything after the stroke. As per the marital status, 103 (76%) were married, 20 (15%) were unmarried, and the remaining 13 (9%) were separated or divorced after stroke. Although the subjects were randomly allocated in either of the groups, the data on the marital status were significantly different. All other components of the demographic data were not significant between the groups. Detail of the demographic data of both the groups of the subjects is enumerated in Table 1.

The result was documented to be highly significant for the majority of the outcome measures among the experimental group compared with the control group. There were favorable changes in the pre and post-intervention scores of both groups, as enumerated in Table 2. The pre-assessment score of FMA-A was 17.36 ± 1.21 and post-intervention, it was significantly (P < 0.001) improved and increased to 26.89 \pm 0.93 and at the time of follow-up assessment, it was minutely reduced to 26.78 ± 0.88. The pre-assessment score of FMA-WH was 8.29 ± 0.96 and post-intervention, it was increased favorably to 14.13 \pm 0.88 and at the time of follow-up assessment, it was minutely reduced to 13.58 ± 0.86 . FMA-UE was favorably raised to 41.32 ± 11.50 from the pre-intervention score of 25.76 \pm 15.26 but it was minutely reduced to 40.40 ± 10.91 at the time of follow-up assessment. However, still, the changes were significant (P < 0.001) and favorably higher among the experimental group as compared to the control group.

The experimental group of subjects recorded to have favorable reduction in the FBP from 1.23 \pm 0.13 to 0.39 ± 0.11 (P < 0.001). The control group of subjects recorded with minor and unfavorably increase in the level of shoulder subluxation and the FBP grade was increased from 1.70 ± 0.13 to 1.77 ± 0.11 .

Table 1: Demographic data.			
Characteristics	Experimental group	Control group	P-value
Age (years)	48.72±15.15	53.41±13.32	0.093
Educational status-Illiterate/Primary/10 th /12 th /	6 (1)/18 (41)/9 (2)/10 (9)/14	13 (21)/28 (35)/6 (17)/1	
Undergraduate/Postgraduate (%)	(28)/11 (19)	(2)/25 (21)/1 (2)	
Gender-Male/Female (%)	43 (63.2)/25 (36.8)	46 (67.6)/22 (32.4)	0.719
Marital status (Married/Unmarried/Separated) (%)	44 (65)/14 (20)/10 (15)	59 (87)/6 (9)/3 (4)	0.01
Socioeconomic-status (BPL/LIG/MIG/HIG) (%)	8 (12)/16 (23)/40 (59)/4 (6)	19 (28)/14 (21)/30 (44)/5 (7)	
Occupational status (Same/Changed/Not doing anything) (%)	13 (19)/3 (5)/52 (76)	7 (10)/0 (0)/61 (90)	0.073
Side of involvement (right/left) (%)	39 (58)/29 (42)	34 (50)/34 (50)	0.492
Handedness (right/left) (%)	39 (58)/29 (42)	34 (50)/34 (50)	0.042
Type of stroke (Ischemic/hemorrhagic) (%)	59 (87)/9 (13)	61 (90)/7 (10)	0.791
Duration (months)	12.04±7.96	13.91±8.08	0.744

Outcome Experimental Control group Experimental Control group Experimental group Control group Experimental group Control group Experimental group F-value P-value P-value PS% CI (Mean Difference) FMA-A 17.36±1.21 15.63±1.21 26.89±0.93 18.29±0.93 26.78±0.88 18.42±0.88 18.42±0.88 18.42±0.88 20.57 <0.001** 3.51-8.54 FMA-WH 8.29±0.96 5.97±0.96 14.13±0.88 8.64±0.88 13.58±0.86 7.85±0.86 13.17 <0.001** 2.054-6.975 FMA-WH 8.29±0.96 5.97±0.96 14.13±0.88 8.64±0.88 13.58±0.86 7.85±0.86 13.17 <0.001** 2.054-6.975 BRS-A 3.02±0.14 4.44±0.11 2.92±0.11 4.44±0.11 2.96±0.11 4.44±0.11 4.44±0.11 4.44±0.11 4.44±0.11 4.44±0.11 4.44±0.11 4.44±0.11 4.44±0.11 4.44±0.11 4.44±0.11 4.44±0.11 4.44±0.11 4.44±0.11 4.44±0.11 4.44±0.11 4.44±0.11 4.44±0.11 4.44±0.11 4.44±0.11	Table 2: Inf	Table 2: Inferential data.								
ure Experimental group Control group Experimental group Control	Outcome	I	Pre	P	ost	Follow-	dn	F-value	P-value	95% CI (Mean Difference)
-A 17.36±1.21 15.63±1.21 26.89±0.93 18.29±0.93 26.78±0.88 18.42±0.88 20.57 <0.001*** -WH 8.29±0.96 5.97±0.96 14.13±0.88 8.64±0.88 13.58±0.86 7.85±0.86 13.17 <0.001*** -UE 25.76±15.26 21.84±19.04 41.32±11.50 26.93±16.01 40.40±10.91 26.16±15.25 19.17 <0.001*** A 3.02±0.14 2.58±0.14 4.44±0.11 2.92±0.11 4.44±0.11 2.86±0.11 45.93 <0.001*** H 2.41±0.16 2.20±0.16 3.66±0.15 2.16±0.15 3.66±0.15 1.85±0.11 44.666 <0.001*** 3.24±0.81 3.56±0.76 2.54±0.78 3.46±0.85 2.53±0.74 3.35±0.78 30.445 <0.001*** 64.32±21.61 50.00±24.88 81.84±15.54 51.75±23.74 81.62±15.79 51.09±24.30 48.21 <0.001***	measure	Experimental group	Control group	Experimental group	Control group	Experimental group	Control group			
-WH 8.29±0.96 5.97±0.96 14.13±0.88 8.64±0.88 13.58±0.86 7.85±0.86 13.17 <0.001*** -UE 25.76±15.26 21.84±19.04 41.32±11.50 26.93±16.01 40.40±10.91 26.16±15.25 19.17 <0.001*** A 3.02±0.14 2.58±0.14 4.44±0.11 2.92±0.11 4.44±0.11 2.86±0.11 45.93 <0.001*** H 2.41±0.16 2.20±0.16 3.66±0.15 2.16±0.15 3.66±0.15 2.16±0.15 25.08 <0.001*** 1.23±0.13 1.70±0.13 0.39±0.11 1.77±0.11 0.42±0.11 1.85±0.11 44.666 <0.001*** 3.24±0.81 3.56±0.76 2.54±0.78 3.46±0.85 2.53±0.74 3.35±0.78 30.445 <0.001*** 64.32±21.61 50.00±24.88 81.84±15.54 51.75±23.74 81.62±15.79 51.09±24.30 48.21 <0.001***	FMA-A	17.36 ± 1.21	15.63 ± 1.21	26.89 ± 0.93	18.29 ± 0.93	26.78 ± 0.88	18.42 ± 0.88	20.57	<0.001**	3.51-8.54
-UE 25.76 ± 15.26 21.84 ± 19.04 41.32 ± 11.50 26.93 ± 16.01 40.40 ± 10.91 26.16 ± 15.25 19.17 $<0.001**$ A 3.02 ± 0.14 2.58 ± 0.14 4.44 ± 0.11 2.92 ± 0.11 4.44 ± 0.11 2.86 ± 0.11 45.93 $<0.001**$ H 2.41 ± 0.16 2.20 ± 0.16 3.66 ± 0.15 2.16 ± 0.15 3.66 ± 0.15 2.16 ± 0.15 2.16 ± 0	FMA-WH	8.29 ± 0.96	5.97 ± 0.96	14.13 ± 0.88	8.64 ± 0.88	13.58 ± 0.86	7.85 ± 0.86	13.17	<0.001**	2.054-6.975
A 3.02±0.14 2.58±0.14 4.44±0.11 2.92±0.11 4.44±0.11 2.86±0.11 45.93 <0.001** (H 2.41±0.16 2.20±0.16 3.66±0.15 2.16±0.15 3.66±0.15 2.16±0.15 2.16±0.15 2.508 <0.001** (H 2.41±0.16 2.20±0.16 3.66±0.15 2.16±0.15 2.16±0.15 2.508 <0.001** (H 3.24±0.81 3.56±0.76 2.54±0.78 3.46±0.85 2.53±0.74 3.35±0.78 30.445 <0.001** (H 4.44±0.11 1.85±0.11 44.666 <0.001** (H 4.44±0.11 1.85±0.11 1.85±0.11 44.66 <0.001** (H 4.44±0.11 1.85±0.11 1.85±0.11 1.85±0.11 1.85±0.11 (H 4.44±0.11 1.85±0.11 1.85±0.11 1.85±0.11 (H 4.44±0.11 1.85±0.11 1.85±0.11 1.85±0.11 (H 4.44±0.11 1.85±0.11	FMA-UE	25.76 ± 15.26	21.84 ± 19.04	41.32 ± 11.50	26.93 ± 16.01	40.40 ± 10.91	26.16 ± 15.25	19.17	<0.001**	5.95-15.75
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	BRS-A	3.02 ± 0.14	2.58 ± 0.14	4.44 ± 0.11	2.92 ± 0.11	4.44 ± 0.11	2.86 ± 0.11	45.93	<0.001**	0.833-1.520
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	BRS-H	2.41 ± 0.16	2.20 ± 0.16	3.66 ± 0.15	2.16 ± 0.15	3.66 ± 0.15	2.16 ± 0.15	25.08	<0.001**	0.650 - 1.498
$3.24 \pm 0.81 \qquad 3.56 \pm 0.76 \qquad 2.54 \pm 0.78 \qquad 3.46 \pm 0.85 \qquad 2.53 \pm 0.74 \qquad 3.35 \pm 0.78 \qquad 30.445 <0.001^{**}$ $64.32 \pm 21.61 \qquad 50.00 \pm 24.88 \qquad 81.84 \pm 15.54 \qquad 51.75 \pm 23.74 \qquad 81.62 \pm 15.79 \qquad 51.09 \pm 24.30 \qquad 48.21 <0.001^{**}$	FBP	1.23 ± 0.13	1.70 ± 0.13	0.39 ± 0.11	1.77 ± 0.11	0.42 ± 0.11	1.85 ± 0.11	44.666	<0.001**	0.77 - 1.41
$64.32 \pm 21.61 50.00 \pm 24.88 81.84 \pm 15.54 51.75 \pm 23.74 81.62 \pm 15.79 51.09 \pm 24.30 48.21 <0.001^{**}$	mRS	3.24 ± 0.81	3.56 ± 0.76	2.54 ± 0.78	3.46 ± 0.85	2.53 ± 0.74	3.35 ± 0.78	30.445	<0.001**	0.44-0.93
	BI	64.32 ± 21.61	50.00 ± 24.88	81.84 ± 15.54	51.75 ± 23.74	81.62 ± 15.79	51.09 ± 24.30	48.21	<0.001**	17.67-31.74

The score of mRS was documented to be favorably reducing among both the groups of the subjects. However, the changes were found to be significantly (P < 0.001) promisingly higher among the experimental group as compared to the control group. Among the experimental group of subjects, the pre-intervention score of mRS was 3.24 ± 0.81 and satisfactorily reduced to 2.54 ± 0.78, and at the time of follow-up assessment, it was minutely changed to 2.53 ± 0.74 . Whereas the score of mRS among the control group was 3.56 ± 0.76 and positively reduced to 3.46 ± 0.85 , and at the time of follow-up assessment, it was minutely reduced to 3.35 ± 0.78 .

The BI scores were favorable and highly increased among the experimental group of subjects. The control group exhibited negligible but positive changes at the time of post-intervention and minutely reduced at the time of follow-up assessment. The score improved to 81.84 ± 15.54 from the pre-intervention score of 64.32 ± 21.61 and further, it was minutely reduced to 81.62 ± 15.79 at the time of follow-up assessment. Still, the experimental group received significant (P < 0.001) and favorably high results as compared to the control group.

FBP method was used to assess pre and post-intervention of both the groups of the subjects. The pre-assessment data were not found to be favorably significant (P < 0.001) among both the groups but post-intervention and follow-up assessment were found highly and favorably significant (P < 0.001) among the experimental group as compared to the control group. The number of subjects without subluxation increased to 42 (61.8%) from 25 (36.8%) at post-assessment among the experimental group subjects whereas the same increased to 17 (25%) from 15 (22.1%) in the control group. The number of subjects at grade 3 of shoulder subluxation was found to be 0 (0%) at the time of post-intervention and follow-up assessment among the experimental group. Only 1 (1.5%) and 2 (2.9%) subjects were observed to be at grade-2 level of shoulder subluxation, respectively, in the experimental group. Among the control group, the number of subjects at grade-3 subluxation is significantly (P < 0.001) very high as 25 (36.8%) and 29 (42.6%) at the time of postintervention and follow-up assessments, respectively. In the control group, the number of subjects in grade 2 slightly increased to 20 (29.4%) from 17 (25%), which again reduced to 16 (23.5%) at follow-up assessment.

DISCUSSION

Upper limb motor impairment is considered to be the most challenging manifestation among post-stroke hemiparetic subjects. Encountering the abnormal coupling of movements is a common hurdle in the path of motor recovery of the upper limb. To arbitrate this challenge, SBMT was applied in a previous study and was concluded to be feasible

BRS-H: Brunnstrom recovery stage-hand, FBP: Finger breadth palpation, mRS: Modified Rankin scale, BI: Barthel index, **Highly significant

among chronic stroke subjects.[18] In the present study, the SBMT as an experimental protocol was compared with the conventional occupational therapy as a control intervention program.

There were positive and significant changes in the postassessment of the experimental group compared with the control group. The stage-specific and synergy-based individual movement training could be the reason for such changes. The stage-specific movements were being provided for the upper limb and the trunk and lower limbs were being used as the reference position during the intervention. Movements were initiated from scapular control and progressed to arm-hand. For each of the prescribed movements, apparent muscular linkages were being refereed and provided. It is mentioned in the literature that post-stroke motor recovery emerges by collaborating with the neural, functional, and synergistic levels.^[32] All three can predicted to be interlinked with each other concerning the management and recovery among the poststroke subjects. This experimental protocol has manipulated the synergy level of concept for the application of motor intervention.^[33] Hence, the motor recovery proceeds from the proximal to distal direction and further from grosser to finer movements of the arm and hand.[34] In addition, the movements will be achieved from simple to complex and from less coordinated to more coordinated in nature. The most strong and crucial motor component is elbow flexion among post-stroke hemiparetic subjects. It could be inferred that without achieving the motor control of elbow extension, stroke subjects cannot achieve the next motor recovery stage of arm and hand. Hence, this motor component is evident to be the most explored in the literature as compared to other movements.[35]

A relation between the synergistic components of the arm and hand was revealed in a correlation study among chronic stroke subjects.[33] A preliminary study was conducted on chronic stroke and the protocol was found to be feasible. Although it was a single group pre-post design, significant changes were observed and proved to be feasible for the chronic stroke subjects.^[18] Considering the safety measures, the acute and sub-acute stroke subjects were not enrolled in that study. The subjects with shoulder subluxation were also excluded, considering it as an additional musculoskeletal complication. Post-stroke shoulder subluxation is considered to be the crucial factor for hampering the motor recovery of the arm and hand. However, this issue is undercover, and there is a lack of evidence-based intervention for post-stroke shoulder subluxation.

Considering the significant observations regarding the synergistic-based motor intervention, some evident-based modifications were being made in the SBMT protocol and this RCT was being conducted. For instance, in this study, the BRS-1 of the arm, acute and sub-acute stroke subjects were also enrolled along with the chronic. The subjects with shoulder subluxation were also included and randomly allocated to either of the groups. The positioning of the trunk and lower limbs was considered as a reference line for the movements of the upper limb. In addition, the positioning of the subjects, stabilization of the body part, and graded dosage of movements were some important modifications in this study.

The neural plasticity and muscle synergies were found to be correlated and recommended to consider it as a physiological biomarker in the recovery pattern. [36]

From contemporary to advanced, a variety of post-stroke rehabilitation techniques are available with varied levels of evidence. Each of the techniques has some or the other advantages and drawbacks. The conventional approaches consider the neurophysiological principles while the recent techniques emphasize principles of motor learning and motor control. Traditional methods are sparsely practiced nowadays, but parts of their principles and techniques are being utilized along with advanced interventions. Among the contemporary intervention techniques, CIMT, mirror therapy, virtual reality (VR), and Repetitive Task training (RTT) carry moderate to high levels of evidence. As per the literature review, there is a large number of overlapping evidence regarding the decision of the most suitable treatment intervention for post-stroke hemiparetic subjects.[37] Considering the motor recovery stage and additional medical manifestations, every technique is not suitable for every stroke subject. VR needs a well well-advanced setup with high economic demands and sound cognitive abilities of the subject. CIMT is only indicated if the subject has achieved wrist extension and thumb release. This will be available at 4 of BRS-WH, and then the subject will be receiving some other intervention. To provide RTT, a fair amount of motor control will be needed, and the subject has to be cognitively sound and medically stable. The structured task-oriented rehabilitation program could not reveal significant results when compared with the conventional program.^[38]

This protocol applies to all the recovery stages, with and without shoulder subluxation and at any of the chronicity levels. This is economical and does not need any extraordinary cognitive demands of the subjects. The findings of this study authenticate to application of the synergistic-based motor intervention for the motor intervention of the upper limb among post-stroke hemiparetic subjects.

Synergistic-based motor intervention can be developed for the lower-limb intervention among post-stroke hemiparetic subjects. Advanced sophisticated assessment tools such as EMG and motion analyzer for synergy measurement and ultrasonography for the subluxation quantification may be utilized for future studies.

Since the study was being conducted in a rehabilitation institute, early stroke subjects were negligible. The study group was not homogeneous in terms of marital status. The subjects with hemorrhagic stroke were proportionally less. The number of subjects with shoulder subluxation was proportionally higher than those without the subluxation.

CONCLUSION

The normal synergistic linkage gets occluded and peculiarly coupled in an anomalous pattern among stroke subjects. Utilizing the evident normal linkages of muscles, the experimental intervention was provided. The "Synergistic-Based Motor Therapy" concluded to be highly superior and significant to the conventional or control intervention program in enhancing upper-limb recovery. Further, the grade of shoulder subluxation was also found to be significantly reduced among the SBMT group participants in comparison to the control subjects. The study authenticates that utilizing the synergistic linkage of muscle can be a promising method of motor intervention among post-stroke hemiparetic subjects.

Ethical approval

The study was approved by the Institutional Ethical Committee of PDUNIPPD, New Delhi (Approval number Code No. : IEC13/2023/RP1) and Ethical Committee of Santosh Deemed to be University (Approval number: SU/2023/068/ [7], Ghaziabad, Uttar Pradesh. Trial Registration: Study was registered under the Clinical Trial Registry of India Registration number: (CTRI/2023/10/058803).

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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