Combit Vs HABIT: Improvement in Tone and Function of Hemiplegic Upper Limb - A Randomized Comparison Trial

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Abstract

Background: Hemiplegia following stroke leads to impairments in tone and motor function of the affected upper limb. Recently, Constraint-induced Movement Therapy (CIMT) and Bimanual Training (BIT) has been proved to have a positive effect on upper limb function. But these approaches have limitations in the clinical application of transfer of function. A hybrid model of therapy combining the effects of CIMT and Bimanual training needs to be studied. Combined Modified Constraint-induced Movement Therapy along with Bimanual Intensive Training (COMBiT) a form of distributed practice model needs to be compared with a standard Practice Hand Arm Bi Manual Training (HABIT) model to determine its effectiveness.

Objective: To study the effects of training utilizing a distributed practice model with three weeks of mCIMT followed by one week of BIT over a standard 4-week HABIT program on tone and function of Hemiplegic upper limb.

Method: Thirty patients wererandomly allocated into two groups, Group A- COMBiT Group and Group B- HABIT Group with 15 patients in each group. Modified Ashworth Scale (MAS), Fugl-Meyer Assessment (FMA), Functional Independence Measure (FIM), Frenchay Arm Test (FAT), Grip Strength (GS), Nine Hole Peg Test (NHPT), and Finger Tapping Rate (FTR) were measured as Pre-test and post-test scores.

Results: With-in group comparisons showed significant reductions in spasticity in both groups. Significant improvements in function were noted in FMA, FIM, FAT, GS, NHPT and FTR. COMBIT had significant improvement on MAS, FIM, FAT, GS, NHPT and FTR.

Conclusion: From the findings of this study it can be concluded that COMBiT, a distributed practice program can be more useful in reducing spasticity and improving Upper limb function when compared with a structured program like HABIT.

Key Words: Stroke, Hemiplegia, upper extremity rehabilitation, modified CIMT, Bimanual training, distributed practice, standard practice, dose

INTRODUCTION:

Stroke or Cerebrovascular Accident (CVA) is the rapid onset of deterioration of the neurological function of a person due to disruption of the blood supply of the brain. The neurological signs must be present for at least 24 hours to be categorized as a stroke. It is one of the most common causes of disability in the adults, with 70–85% of first strokes causing hemiplegia¹. The prevalence rate of stroke in India is 147/100,000 with yearly incidence of $36/100,000^2$. Higher prevalence was observed in women than in men with 564/100,000 in women and 196/100,000 for men. Around 60 % of stroke patients underwent neuroimaging in which around 68% of strokes are due to infarcts and around 32 % of the strokes are due to haemorrhages. The compiled findings of prevalence studies show the range between $147-922/100,000^{3.4}$.

In developing countries like India, stroke leads to early mortality and permanent disability due to varied demography, coupled with an increasing incidence of modifiable risk factors, this along with low income causes a burden on the amount spent on rehabilitation^{5, 6}. Around 60% of hemiplegics who need inpatient rehabilitation have achieved functional independence in simple activities of daily living (ADL) such as toileting and walking short distances after six months following a stroke^{7, 8}. Majority of stroke survivors have motorimpairments in the upper limbwith loss of elbow extension due to spasticity or muscle weakness^{9, 10}. This leads to impairments in Activities of Daily Living (ADL), occupational tasks and leisure activities¹¹. The impairmentsinclude muscle weakness, sensory impairment, impairment in muscle function, and loss of dexterity, ^{12,13} severely impacting the patients' daily life further affecting the quality of life of the patient following stroke ^{14, 15}. Thus, restoring upper-limb function is significant.

Various retraining strategies exist in stroke rehabilitation including explicit and implicit methods to train function¹⁶. CIMTis one of the most commonly used approach recently, it is based on the principle that training facilitates cortical excitability and improves sensorimotor recovery ^{17,18}.Nevertheless, CIMT has limitations inits application as a standard rehabilitation practice, as few patients have difficulty tolerating forced non-use of normal limb, high intensity practise demands of affected limb and compliance problems on part of both the patient and clinician ¹⁹. Therefore, Modified CIMT (mCIMT) was proposed utilizing distributed practice and activities for both paralytic and nonparalytic upper limbs. This current study uses a hybrid model combining modified constraintinduced movement therapy (mCIMT) followed by intensive bimanualtraining (called COMBiT).Hand-arm bimanual intensive training (HABIT)was designed specificallyfor the upper extremity in children with unilateral cerebral palsy, which showed significant improvements in upper limb function when compared with CIMT. HABITincorporates symmetrical and asymmetrical movements and practice of tasks based on principles of motor learningand neuroplasticity. Progression is made by increasing complexity and repetition of the functional activities with use of both hands 20 .

This study aims to assess the efficacy of the COMBiT model (3 weeks of 90 hours of mCIMT followed by one week of 30 hours of bimanual training) and HABIT model (practice for 4 weeks standard care delivered at individualized level)and compare their effectiveness.

Materials and Methods

Thisrandomized prospective experimental trial was conducted in theDepartment of Neurology, MSS HOSPITAL, UNIT OF SHRI MULTAN SEWA SAMITI, Delhi for a period of one year between September 2018 to August 2019. This study was approved by the Institutional Ethics Committee (REF-SBS/SOP/2018/09), Approval was also taken from the Hospital (REF-MSS/PHY/2018/18) and patients for the study.

Inclusion criteria

1. Patients with first strokebetween 45-75 years diagnosed clinically and/or confirmed by radiodiagnosis (CT scan, MRI scan), with stable vitals and a GCS score >8. And provide with and informed consent personally or by a proxy.

- 2. Sub-acute or chronic stroke with more than three months from onset with impaired upper extremity function, and upper-limb muscle strength that exceeded level 2 on the Medical Research Council muscle scale; and not exceeding grade 2 in Modified Ashworth scale.
- 3. Able to grip objects with a paralysed hand.
- 4. Wrist extension >20°, MCP (Metacarpophalangeal) joints >10° (Taub et al., 1993)²¹
- 5. Normalcognition with a Mini-Mental State Exam score ≥ 24 .

Exclusion criteria

Multiple Stroke, Aphasia or Speech Defects, Severe cardiopulmonary complications, Pre-Existing Upper limb Impairments prior to stroke, Deterioration of current condition preventing the patient from resumingrehabilitative training.

Sampling

Sixty stroke subjects were screened according to inclusion and exclusion criteria and 30 subjects were selected who were randomly (Patients were allotted numbers from 1 to 30, Randomly 15 chits were taken out of pool of 30 and those numbers were matched with numbers of patients who were allocated into Group A and rest 15 were allocated Group B) divided into two groups, Group A (COMBiT Group) and Group B (HABIT Group) of 15 each.

Variables

Dependent variables

- Modified Ashworth Scale (MAS)
- Fugl-Meyer Assessment (FMA)
- Functional Independence Measure (FIM)
- Frenchay Arm Test (FAT)
- Grip Strength (GS)
- Nine Hole Peg Test (NHPT)
- Finger Tapping Rate (FTR)

Independent variables

- Combined mCIMT and Bimanual Intensive Training
- Hand-Arm Bimanual Intensive Training

Materials used

Mat Table, Table, Chair, Pen / Pencil, Paper sheet, Reflex Hammer, Cylinder (small can or jar), Goniometer, stopwatch, Blindfold. Bedside Table, Ruler, Cylinder (12 mm diameter, 5 centimetres long), Sprung clothes peg, 15 cms Dowel, comb, Jamar Dynamometer, Board (wood or plastic): with 9 holes (10 mm diameter, 15 mm depth), A container for the pegs, 9 pegs (7 mm diameter, 32 mm length) and stopwatch.

Material for Interventions- Full Arm Glove, Crepe Bandage, Arm Sling, Pegboard,Pegs, Glass, Hair Brush, Sprung clothes peg, Bottle, Towel, Jar, Physio ball large and medium, Volleyball, Smiley ball, wheelchair, string beads, coins, playing dough, Paint Brush, Electrical Switches, Pencil, Table, Chair.

Procedure

Group A- COMBiT Group

mCIMT: In mCIMT, the unaffected arm is constrained in an individually made glove reinforced with a crepe - bandage and Arm sling and maintained at resting position beside the trunk. During intensive training of the affected upper limb, the unimpaired upper limb is tied to a wheel chair or chair or bedside. This method for unaffected upper limb is followed for 6 hours a day for 3 weeks (90 Hours).

This was combined with intense practice of tasks to promote the use of the impaired arm for 3 hours during this period (45 Hours)²².Guided movements for the affected upper limb are performed, Activities focusing in improving strength, gross motor and fine motor control are practised. TheraBand, grip power and Therapeutic putty were used for muscle strengthening, Throwing and catching the ball, and cup shifting activities were used for improving gross motor control, Peg-boards and Block construction were used for improving fine motor control²³.

Bimanual Intensive Training²⁴:Intensive Bimanual Training was performed after mCIMT of 3 weeks. The training was given for 3 hours a day for 1-week (15 Hours) Activities included:

Dough activities, Ball activities, Cubesactivities, Bottle and marble activities, stackingrings, stringing beads, usingscissors to cut paper, Boxshifting, Armcycle ergometer, Towel folding, Opening and closing a jar, Wheelchair propulsion.

Group 2- HABIT Group

Subjects in this group were treated with Hand-Arm Bimanual Intensive Training³³. The protocols for HABIT group were used for 3 hours a day for 4 weeks (60 Hours): Activity included the same as was given in bimanual training of COMBiT group.

STATISTICAL ANALYSIS

Data was collected on the baseline pre-intervention and the last day of the 4^{th} -week post-intervention. Mean and Standard Deviation scores of the groups were used for comparisons. SPSS version 22.0 was used for analysis.Data analysis included Descriptive characteristics of the subjects, Within-group comparisons, and Between-group comparisons. Kruskal Wallis test and Mann Whitney U test were applied for within and between-group comparisons of MAS, FMA, FIM, FAT, NHPT, and FTR.Students Paired and unpaired t-tests were used for with-in and between-group comparisons of Grip strength. Data was analysed at 95% CI and P< 0.05 was considered as significant.

Results:

Thirty subjects were randomly allocated into two groups to study the effects of COMBiT And HABIT protocols on the tone and function of the hemiplegic upper limb. Multiple baseline characteristics of the patients in both the groups show homogeneity withnon-significant differences at the baseline [Table1].

	COMBiT	HABIT	P-Value	
Age* (In Years)	59.73 <u>+</u> 7.51	59.27 <u>+</u> 9.07	0.879	
Gender		I I		
Males, n (%)	12 (80)	12 (80)	1.000	
Females, n (%)	3 (20)	3 (20)		
Type of stroke		<u> </u>		
Ischemic, n (%)	13(86.7)	11(73.3)	0.369	
Haemorrhagic, n (%)	2(13.3)	4(26.7)		
Duration of stroke		<u> </u>		
3-6 months, n (%)	7(46.7)	5 (33.3)	0.255	
>6 months, n (%)	8(53.3)	10 (66.7)		
Mean Duration	6.93 <u>+</u> 2.28	8 + 2.73		
Side of stroke				
Right, n (%)	8 (53.3)	6 (40)	0.472	
left, n (%)	7 (46.7)	9 (60)	-	

Table 1: Shows	baseline character	istics of the study p	population in both groups.
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*Represents continuous variable with normal distribution, expressed as mean ± SD; other values are expressed as n (%); COMBiT (COmbined Modified constraint-induced movement therapy and Bimanual Intensive Training), HABIT (Hand Arm Bimanual Intensive Training).

Comparison of pre and post readings suggest significant differences within both the groups with improvements in mean and SD values of the primary and secondary outcome measures. The analysis of MAS at baseline showed a significant reduction in tone in 4th week when compared with preintervention in both COMBiT and HABIT groups with p < 0.05 [Table 2]. The between-group comparison showed significant differences with z = -2.061 and p < 0.05 suggesting that improvements in tone with COMBiT protocol are more effective than HABIT protocol. Thus, improvement in tone reveals a reduction in spasticity after both the interventions [Table 3]. The analysis of the FMA scale at baseline showed significant reductions in Functional impairment in COMBiT Group with z=-3.408 and p<0.05 after 4 weeks and with z=-3.411 and p<0.05 HABIT Group also showed a significant reduction of impairment [Table 2]. Between-group comparison did not show a significant difference for post FMA scores suggesting similar effects of both protocols in improving Function [Table 3].By analysing the FIM scales for functional independence with the baseline, Both COMBiT and HABIT groups showed significant improvement after 4 weeks with z=-3.415, p<0.05 for COMBiT and z=-3.411 and p<0.05 for HABIT group [Table 2]. A comparison of FIM scores between the groups showed significant differences with z = -2.077 and p < 0.05 [Table 3]. Analysis of FAT scores on baseline showed significant improvements in the Task function of Upper Limb after 4 weeks. COMBiT Group showed significant improvement with z = -3.496, p<0.05 and HABIT Group also showed significant improvement with z= -3.256, p<0.05 [Table 2]. A comparison of FAT scores between the groups also elicited significant differences with z = -3.258 and p < 0.05 [Table 3]. Withingroup comparison of Grip strength in both groups showed significant improvements in 4 weeks with t=-11.411, p<0.05 for COMBiT Group and t= -10.940, p<0.05 in HABIT Group [Table 2].

Comparison of Grip Strength score after 4 weeks between the groups showed significant improvements with t= 2.555 and p<0.05.[Table 3]. Analysis of Nine Hole Peg Test score for withingroup comparisons show significant improvements with z= -3.430, p<0.05 in COMBiT Group and z= - 3.453, p<0.05 in HABIT Group [Table 2]. Between-group comparison also showed significant differences with z= -3.222, p<0.05 [Table 3].The analysis of Finger Tapping Rate on baseline showed significant improvements in hand function after 4 weeks in both the groups with z= -3.418, p<0.05 in COMBiT Group and z= -3.42, p<0.05 in HABIT Group [Table 3].

	COMBiT GROUP			HABIT GROUP		
Outcome	Pre-Scores	Post scores	P-value	Pre-Scores	Post scores	P-value
Measures						
MAS	2.87 <u>+</u> 0.52	1.67 <u>+</u> 0.49	.000	3.33+0.61	2.13 <u>+</u> 0.64	.000
FMA	87.73 <u>+</u> 21.14	118.60 <u>+</u> 22.01	.001	77.87 <u>+</u> 12.76	111.8 <u>+</u> 5.53	.001
FIM	106.26 <u>+</u> 10.66	118.73 <u>+</u> 5.40	.000	96.4 <u>+</u> 17.9	108.8 <u>+</u> 12.9	.001
FAT*	1.60 <u>+</u> 1.18	4.07 <u>+</u> 0.96	.001	1.53 <u>+</u> 0.99	2.87 <u>+</u> 0.64	.001
GS*	2.46 <u>+</u> 2.35	13.87 <u>+</u> 5.45	.000	1.53 <u>+</u> 1.88	9.27 <u>+</u> 4.35	.000
NHPT*	2.53 <u>+</u> 2.06	7.47 <u>+</u> 1.55	.001	0.27 <u>+</u> 1.03	5.27 <u>+</u> 1.53	.001
FTR	5.07 <u>+</u> 3.39	17.73 <u>+</u> 5.04	.001	3.13 <u>+</u> 2.64	12.93 <u>+</u> 5.12	.001

 TABLE2. within-group comparison for effects of COMBiT and HABIT.

*Variability of Mean and SD of FAT, GS and NHPT outcomes in both groups are due to complete loss of hand function during pre-intervention measurements due to which zero was awarded to the data. This led to increased SD scores of the group.

Comparison of pre interventional readings between the groups shows Non-significant differences with p>0.05 for MAS, FMA, FIM, FAT, GS, and FTR. Comparison of post interventional readings between the groups showed significant differences with p<0.05 for all the outcomes except FMA which showed no significant differences with p>0.05.

	COMBiT GROUP	HABIT GROUP	t- value/ Z- value	P value
Pre- Treatment				
MAS	2.87 <u>+</u> 0.52	3.33+0.61	-2.134	.067
FMA	87.73 <u>+</u> 21.14	77.87 <u>+</u> 12.76	-1.641	.101
FIM	106.26 <u>+</u> 10.66	96.4 <u>+</u> 17.9	-1.619	.105
FAT	1.60 <u>+</u> 1.18	1.53 <u>+</u> 0.99	-0.261	.794
GS	2.46 <u>+</u> 2.35	1.53 <u>+</u> 1.88	1.198	.241
NHPT*	2.53 <u>+</u> 2.06	0.27 <u>+</u> 1.03	-3.204	.001
FTR	5.06 <u>+</u> 3.39	3.13 <u>+</u> 2.64	-1.642	.101
Post- Treatment				
MAS	1.67 <u>+</u> 0.49	2.13 <u>+</u> 0.64	-2.061	.039
FMA-UL	118.60 <u>+</u> 22.01	111.8 <u>+</u> 5.53	-0.686	.492
FIM	118.73 <u>+</u> 5.40	108.8 <u>+</u> 12.9	-2.077	0.038
FAT	4.07 <u>+</u> 0.96	2.87 <u>+</u> 0.64	-3.258	.001
GS	13.87 <u>+</u> 5.45	9.27 <u>+</u> 4.35	2.555	.016
NHPT	7.46 <u>+</u> 1.45	5.27 <u>+</u> 1.53	-3.222	.001
FTR	17.73 <u>+</u> 5.05	12.93 <u>+</u> 5.12	-2.4	.016

TABLE3. Effect of COMBiT and HABIT on primary and secondary outcome measures (N=30).

* NHPT showed significant differences. This can be attributed to recording zero scores if the subject was unable to place even a single peg in 50 seconds. Only four subjects in the HABIT group were able to place any number of pegs when compared to the COMBiT group in which ten subjects were able to place at least one peg.

Figure 1: shows the outcomes of the study. X-Axis shows duration and Y-Axis shows changes in the scores in both groups expressed in two colors, Blue shows recordings in COMBiT Group and Orange shows recordings in HABIT Group.



Discussion

From the results it can be stated that both the strategies were effective in improving tone and function within their groups with significant differences between the Pre and post interventional scores after a 4-week intervention. comparison between baseline and post-treatment scores showed significant improvements in both groups for all outcome measures.

COMBiT Group

Modified constraint-induced movement therapy utilizes task repetition as a motor rehabilitation approachthat facilitates recovery and promotes changes in the neuromuscular system²⁵. Classical CIMT incorporates maximum constraint of the unaffected limb for a majority of the waking hours and patients have difficulty in tolerating this²⁶. Further traditional CIMT doesn't allow for the use of bimanual tasks even when the goals identified by the caregivers tend to be bimanual^{27, 28}. Further, Taub and Wolf²⁹ used CIMT for unaffected Limb constriction during 90% of the time that the patients are awake.^{30, 31}mCIMT varies from CIMT in dosage, timing, and composition of therapy. These modifications are typically characterized by distributed training protocols with reduced time spent in training, less time during which the Non-Paralytic Upper Extremity is restrained, and absence of a transfer.^{32, 33}Treatment sessions for mCIMT varies from 30 minutes to 6 hours perday, 2-7 sessions a week for 2-12 weeks³⁴. Improvements in the functional tests onhemiparetic upper limb who generally do not use their weak upperlimbs spontaneously, can be due to availability ofmovement at pre intervention stage. The immobilization of Normal limb facilitated the use of affected limb to produce additional benefits to these patients.³⁵

Improvements in FAT, GS, NHPT, and FTR can be attributed to the improved motor function of the affected arm, reductions in spasticity, enhanced upper limb control during use in daily life and ADL. This is consistent with the findings of Kwakkel G, Veerbeel J M, et.al, (2015) who found significant positive small to medium summary effect sizes in terms of muscle tone, motor function, arm-hand activities, self-reported amount of arm-hand use in daily life and basic ADLs after treated with mCIMT.mCIMT approach may also improve the hand function by increased short term^{36, 37} and long-term cortical activation patterns³⁸. This also in conjunction with wolf, 2007, found improved hand function to be associated with increased recruitment of the ipsilateral somatosensory cortex. ^{39,40, 41}

The significant improvement in movements, reflected by FMA scores, in the mCIMT group suggests that mCIMT training improved motor control of the upper limb This improvement is attributed to the forced use phenomenon to overcome learned non-use by facilitation activation of cortical regions.⁴²The results of our study have demonstrated that this protocol of mCIMTwas associated with greater improvement in motor control and daily functioning than conventional rehabilitation methods. These results were consistent with the previous studies.^{43,44}

HABIT Group

Hand-arm bimanual intensive therapy (HABIT) is a form of intensive bimanual training focused on improving the amount and quality of involved hand-use within the context of bimanual tasks.^{45, 46}

HABIT training focused on the progressive complexity of structured practice and bimanual upper limb use for functional activities. The subjects are required to perform motor tasks with both upper limbs, recovery is facilitated by active use of both the extremities to perform a task.⁴⁶Bimanual training improves the temporospatial control of the two hands which are affected in hemiplegia due to brain damage.⁴⁷ The areas controlling bimanual coordination and are located in supplementary motor areas and parietal lobe.^{48,49} Bimanual intensive training of Upper limbs activates interhemispheric disinhibition allowing reorganization within the areas of brain undamaged in stroke. This occurs to assist the formation of new task-relevant neural networks required to perform simultaneous bimanual tasks.⁵⁰This explains reductions in spasticity seen with HABIT training post-intervention and also explains the significant improvements in motor functional scales which require motor control in upper limbs to produce positive results. Similar findings are noted by Wahab, Hamed, (2014), who reported improvements in hand control with BIT and related it to activation of neural networks in both hemispheres.²⁴ Improved function is also due to increased interhemispheric communication and ipsilateral activation of the motor cortex of the affected hemisphere.^{50, 51}Motor learning principles would suggest that improvement in the use of two hands together maximized by repetitive practice of bimanual goal-directed tasks.⁵²

Significant between-group findings can be explained by the effects of distributed practice on impaired upper limb in the COMBiT group.Implicit neural mechanisms facilitate plasticity which was further reinforced by coordinated bi-dextrous simultaneous practice.In the HABIT group, standard practice improved function by facilitating the proximal musculature controlled by bilateral outputs by descending corticospinal pathways. So, activities requiring proximal muscle control would have gained more from bimanual intensive training.

As a single-centre study, this study primarily explores the possibility of these protocols before a large-scale clinical trial can be conducted. The long-term prognosis and suitability to varying dysfunctions of the upper limb in stroke need further investigation.

Limitations may involve lack of long-term follow-up and use of retention tests at different periods to test the level of carryover of motor control following training, studies correlating cortical mechanisms with motor recovery must be conducted more thoroughly using technology and variables from all levels of ICF model can be used to note for influence.

Conclusion

From the findings of this study, it can be concluded that distributed practice along with intensive training of both upper limbs as delivered by COMBiThas a positive effect on the tone and function of the hemiplegic upper limb when compared to a structured training program.

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Declaration of Interest statement: The Authors declare that there are no competing interests.

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Images showing Measurement of outcomes

Images showing intensive practice of Affected upper limb in COMBiT Group



Images showing Bimanual intensive training in Both groups



