original article

Comparison of Task Oriented Therapy and Modified Constraint Induced Movement Therapy along with Functional Electrical Stimulation to Improve Hand Function In Sub Acute Stroke survivors: a Randomized Control Trial

Nainky Bhalla[1], Navkaran Shergill[2]

[1]Research Scholar, [2]Assistant Professor, Department of Physiotherapy, RIMT University, Gobindgarh, Punjab.

Abstract

Background: The study aims to investigate the effectiveness of 6 weeks of two-channel functional electrical stimulation assisted hand training along with Task Oriented Training and Modified Constraint Induced Movement Therapy on the restoration of hand function in subacute stroke patients. **Trial design**: A Multi–group pre test–post test design randomized controlled study was conducted with 30 individuals with upper-limb motor impairment after stroke. **Method**: Participants was randomly assigned into three groups FES-TOT, FES- mCIMT and FES-Ctrl groups. All participants were treated for 90 minutes a day, 5 times a week for 6 weeks. Hand function was assessed by Action Research Arm Test score (primary outcome), Grip strength, Pinch strength and Stroke Impact Scale (secondary outcome). **Result**: There was statistical significance ($p<.05$) between the groups for ARA and Grip strength outcome measures. It was found that subjects in both experimental groups (but FES-TOT > FES-mCIMT,) showed more improvement in ARA score and grip strength (lateral pinch and three jaw chuck pinch) as compared to control group (FES-CTRL). **Conclusion**: It is concluded that training with FES along with TOT is more effective in improving Hand function and grip strength as compared to mCIMT and conventional hand rehabilitation. However studies with large sample size are required for generalizability of the finding based on statistical analysis.

Trial registration: Clinical Trial Registration India CTRI/2019/06/019940 dated 28 June 2019.

Keywords*: Stroke, Functional Electrical Stimulation, hand function, dexterity, rehabilitation.*

Introduction

Stroke causes hand function impairment, which consists of two complementary characteristics: strength as in a power grip and control of individual finger movements as in piano play. [1, 2] Difficulties in opening the hand willingly, extending the wrist and fingers against resistance, and generating powerful grip are frequently noted after stroke. [3,4] Loss of finger control is an inability to either move one finger while maintaining the other fingers immobile or to create complicated hand gestures that impairs the capacity to execute duties such as typing or buttoning a shirt. [1,2,5] When strength recovers after stroke, control is often impaired, causing permanent impairment. [6,7]

Conventional hand rehabilitation methods are efficient in decreasing the individual's disability, but there are constraints in improving and recovering upper limb activities. The two most popular techniques for enhancing hand function used are modified constraint induced movement therapy (mCIMT) & Task Oriented Therapy (TOT). The mCIMT is a unilateral, manual and repetitive intervention training in which the normal limb is restricted and the patient is forced to recruit the affected hand to carry out various repetitive activities.

Corresponding author:
Nainky Bhalla
Research Scholar, Department of Physiotherapy, RIMT University, Gobindgarh, Punjab
email:nainky@gmail.com

Task oriented training is a goal oriented program where different activities that could be functional or imitating functional activities are performed bilaterally by the patients. Nowadays, technology is emerging as an adjunct to therapy in rehabilitation. FES is a promising therapy which has shown to improve arm and hand function in individuals with stroke, but evidence is mostly limited.

The International Classification of Functioning, Disability and Health (ICF) is a classification system , which indicates complex interactions between a person and his/her physical, social and psychological environment and addresses the influence of such system on person's health status.[8] The ICF, introduces a paradigm shift in how disability is conceptualized and, at the same time, provides a classification based on this understanding to describe relevant aspects of health and its determinants to be used for standardized reporting of information on health and disability in clinical practice and research. Body function, body structures, activities, participation, and environmental factors are classified based on ICF categories. [9] Thus, the purpose of this randomized controlled trial (RCT) is to follow the ICF guidelines and therefore hand function is assessed by means of ARA test to measure the activity level .The body structure and function level of ICF was examined by Hand grip and pinch strength. Stroke impact scale is used to measure the impact of treatment on participation.

Objectives

The study aims to investigate the effectiveness of 6 weeks of two-channel functional electrical stimulation assisted hand training along with Task Oriented Training and Modified Constraint Induced Movement Therapy on the restoration of hand function in subacute stroke patients.

Methods: Participants, interventions and outcomes

Study setting and ethical clearance

The present study is a randomised controlled three-armed parallel design recruiting 30 individuals with upper-limb motor impairment after stroke. Participants were recruited after discharge from hospital and up to 6 months post-stroke. The study was carried out neurological physiotherapy OPD of the institute. The ethical approval for the study was taken from the Ethical committee of the RIMT institute.

Eligibility criteria

Participants were included in this study if they:

· are unilateral /first time ischemic stroke /right or left

· Between 6 weeks and 6 months post stroke

· Age group between 40-75 years

· MMSE more than 23, Modified Ashworth scale score >1and <3.

· Voluntary extension of wrist and fingers of at least 10 degrees from the resting position. Functional level (FMA-UE score >22 to 58).

· Brunnstrom stage of motor recovery of 2 to 5.

Participants were included in this study if they:

· are above 75 years of age

· Wrist and/or finger contracture or joint stiffness

· Presence of implanted electronic devices, epilepsy, respiratory insufficiency, pregnancy, peripheral neuropathies, cutaneous ulcers at the stimulation zone.

· Brunnstrom stage of motor recovery of 1

· Neuropsychiatric disorder, pain in wrist and hand

Recruitment

The subjects who fulfilled the inclusion and exclusion criteria and written informed consent, were randomly assigned one of the three groups .To reduce selection bias effect model of random allocation sequentially numbered opaque sealed envelope (SNOSE) was used. Patients entered into either the intervention group or the control group based on the study group allocation

Interventions

Subjects were informed about the study and a written informed consent was taken . The duration of treatment session was 90 min which included FES (30 min) , mCIMT (30 min) or TOT (30 min) and conventional

physiotherapy (30 min) treatment for 5 days a week for 6 weeks .

In Control Group (FES with Conventional Physiotherapy)

Subjects were treated with a combination therapy of conventional physiotherapy and functional electrical stimulation for a total duration of 60 minutes. FES was applied on the wrist extensors of affected upper limb for 30 min. The subject was instructed to perform task specific grasping and releasing of a half-litre bottle. Rest period was given for every 15 repetitions**.** Subjects was treated with a conventional physiotherapy for 30 mins Conventional exercises included are Range of motion exercises , gait training , and cycling[10]

In Experiment Group A (FES with TOT)

Subjects were treated with a combination therapy of task oriented therapy (30 min), functional electrical stimulation, consisting of two tasks (30 min) and conventional therapy (30 min), for a total duration of 90 minutes. The task-oriented training was bilateral arm training which included eating (using a cup and spoon), dressing (wearing and taking off a kurta, tying turban), personal hygiene (using a towel, combing, tooth brushing), and standing up and sitting down (standing up from and sitting down on a chair,car).The treatment protocol was made according to the Indian culture and occupational habits for Indian stroke population. The training was carried out for 30 min per day for 5 days per week for 6 weeks.[11]

In Experiment Group B (FES with mCIMT)

Subjects were treated with a combination therapy of Modified constraint movement therapy (30 min), functional electrical stimulation (30 min) and conventional therapy (30 min), for a total duration of 90 minutes.

Shaping and adaptive and repetitive task practice techniques will be used during the training sessions. Therapy consists of gross arm movement, grasp/grip and in hand manipulation will concentrate on the affected limb during the 6-week period, the patients' unaffected hands and wrists were placed in mitts with self-adhesive (Velcro) straps every weekday for 6 hours identified as a time of frequent arm use. [12]The training was carried out for 30 min per day for 5 days per week for 6 weeks. .

Participant received 30 training sessions, each 1.5 hour long, with a physiotherapist over 6 weeks to give a total of 45 hours of training time per participant.

Outcomes

Primary Outcome Measures included the activity level of ICF Hand function which was assessed by means of Action research arm (ARA) test. Secondary Outcome Measures included the body structure and function level of ICF which was examined by Hand grip and pinch strength by dynamometer three times and the mean of each value was scaled in kilogram.[13-15] Stroke impact scale was used to measure the impact of treatment on participation sub part of ICF. The participants underwent clinical evaluation of ARAT, Grasp and Pinch Strength and SIS before treatment and at 3wk and 6 week after treatment to evaluate the difference between groups

Statistical Methods and Results

Sample characteristics

The data was analyzed by SPSS Version 20.0. Normality of the collected data was analyzed with Shapiro Wilk test .Normally distributed continuous variable were summarized as mean and standard deviation. Repeated measure ANOVA was used to establish the statistical significance among baseline, 3wk and 6 wk. P value ≤ 0.05 was considered as statistically significant.

The demographic and clinical features of the 30 patients with post-treatment evaluation are shown in Table 1. The mean age of the subjects at the baseline visit was 59.17(± 12.54) years and mean time since stroke of 6.07(±3.07) months. Males predominated in all the groups, and ischemic stroke was the most common type.

Table1: Demographic characteristics of sample

Demographic dimensions	FES-mCIMT gp	FES-TOT gp	FES-CTRL gp
Age	55	53.8	68.7
Sex	M>F(2)	M	M>F(3)
Onset of stroke	7	5.5	5.9
Dominance	Rt>Lt	Right	Rt>Lt
Side of stroke	5 Lt,5Rt	5 Lt,5Rt	6Rt,4Lt
Type of stroke	Hemorrhagic& Ischemic	Hemorrhagic& Ischemic	Hemorrhagic& Ischemic
No. of subjects	10	10	10

The sample was compared for outcome measures- ARA test, SIS test and Grip Strength on baseline with 3wk and 6 wk post intervention variable using repeated measure ANOVA to establish the statistical significance. P value ≤0.05 was considered as statistically significant

Table2; Comparison of outcomes between Baseline, Post intervention 3 and 6 week (T0,T1 and T2)

Outcome measures	Groups	T0	T1	T2	P -value
ARA	FES-mCIMT	22.5(±15.2)	25.6(±15.44)	30.7(±16.33)	.000
	FES-TOT	34.3(±9.7)	39.6(±10.0)	45.9(±9.89)	.000
	FES-CTRL	28.7(±16.35)	31.1(±15.9)	34.2(±16.4)	.000
SIS	FES-mCIMT	38.61(±17.34)	40.25(±17.7)	42.36(±19.06)	.000
	FES-TOT	44.12(±13.51)	50.02(±13.90)	55.14(±13.00)	.000
	FES-CTRL	38.58(±13.57)	42.0(±14.91)	44.10(±15.42)	.000
Grip Strength	FES-mCIMT	4.71(±5.99)	6.75(±6.6)	9.56(±7.5)	.008
	FES-TOT	14.96(±11.07)	17.43(±10.55)	20.58(±10.56)	.001
	FES-CTRL	6.25(±5.61)	7.34(±5.36)	9.47(±5.31)	.001

p- value is significant at<.05

The sample was then compared between the 3 groups for outcome measures- ARA test, SIS test and Grip Strength using one way ANOVA to establish the statistical significance. P value ≤0.05 was considered as statistically significant.

Table3: Comparison of outcomes between the three groups

ARA	P-value	SIS	P-value	Grip strength	P-value
Baseline(T0)	.111	Baseline(T0)	.633	Baseline(T0)	.016*
PI -3Wk(T1)	.000*	PI -3Wk(T1)	.323	PI -3Wk(T1)	.008*
PI -6Wk(T2)	.000*	PI -6Wk(T2)	.194	PI -6Wk(T2)	.006*

PI:Post intervention,*p- value is significant at <.05

There was statistical significance(p<.05) between the groups for ARA and Grip strength outcome measures, but no improvement was seen in SIS score. ARA showed statistical significance (p=.000) and Grip strength showed significant improvement (p=.006).It was found that subjects in both experimental groups(FES-mCIMT,FES-TOT) showed more improvement in ARA score and grip strength (lateral pinch and three jaw chuck pinch) as compared to control group (FES-CTRL).

Discussion

The study showed that all the three groups had significant improvement in hand function, the proportion of clinically meaningful improved subjects, denoted as an improvement of 5 points or more on the ARA test. The mean difference between TO and T3 for ARA outcome was found 8.2 points in the FES-mCIMT group (3.2 points higher than MCID),11.6 points in the FES-TOT group(6.6 points higher than MCID) and 5.5 points in FES-CTRL group(.5 points higher than MCID).

These finding are in accordance with review of literature done on the influence of FES on hand motor recovery in persons after stroke. The general conclusion is that , while these are indication of benefit for hand function, strong evidence is still missing especially when compared to other valid therapies such as TOT and mCIMT, used in the present study[16-18](Nudo et al.,2001;Pomeroy et al.,2006; Quandt & Hummel,2014)

Table 4: Number of Improved Patients T0-T2 (Pre-Post Treatment)

			FES-Mcimt(n=10)	FES-TOT (n=10)	FES-CTRL(n=10)
ARA (0-57)	T0 (Pre score)	<10 points	1	0	2
		<20 points	3	1	1
		>20 points	6	9	7
	T2 (Post score)	<15 points	0	0	1
		15-30 points	4	1	2
		30-57 points	6	9	7

Further, while at baseline FES-mCIMT group with a median Pre assessment ARAT score of 28.5 (FES-mCIMT) , 38.5(FES-TOT),15.5 (FES-CTRL) can be described as having good arm and limited hand capacity as classified by Nijland et al.,2010, and the post assessment the ARA score of 42.50(FES-mCIMT) , 44.50(FES-TOT),23.50 (FES-CTRL) indicating that from being a group with limited hand capacity they had arrived at being a good arm-hand capacity group.

There was also a significant reduction in hand deficit in three groups as denoted by the grip strength with a change in group median score from 2.26 points to 9.5 points in (FES-mCIMT) , 14.74 points to 23.12 in (FES-TOT),2.26 points to 6.12 (FES-CTRL) There was thus a trend for bigger change in favor of the (FES-mCIMT) and(FES-TOT), group indicating that adding mCIMT and TOT to a conventional protocol may have greater effect at the neuromotor level of arm and hand function than usual care.

Subacute patients are, however, more likely to have an improvement in response to whichever treatment, due also to concomitant spontaneous recovery [19-20](Langhorne, Coupar & Pollock ,2009; Veerbeek et al.,2014). In the present study there appeared to be a further beneficial effect of adding electrical stimulation to the treatment protocol for the subacute participants, with approximately 21% (N = 7/30) improving 12 points or more on the ARAT ,73.3% (N = 22/30) improving 5 points or more on the ARAT and 0.3%(N = 1/30) scored less than 5 points on ARAT scale.

Conclusion

It can be concluded that training with FES along with Constraint Induced Movement therapy, Task oriented therapy and Conventional therapy showed clinical improvement in hand function in sub acute stroke .It was also found that mCIMT and TOT is effective in improving Hand function and grip strength as compared to conventional hand rehabilitation. However studies with large sample size are required for generalizability of the finding based on statistical analysis.

The outcomes of this study will help us the design of a fully powered randomized controlled trial to evaluate the effectiveness of FES with traditional hand rehabilitation techniques in improving power grip and finger individuation. As it is found to be effective, potentially, we might get an ideal hand rehabilitation technique to be used along with FES for improving motor hand function in stroke.

Conflict of Interest : Nil.

Funding: Not Funded

Ethics approval and consent to participate :

Ethical approval for the study was taken from the Institutional Ethical Committee (IEC) RIMT university,Mandi Gobindgarh,Punjab-147301.Ref /No/ Phd/Gen/2019/21 dated 10 May 2019.

The consent form includes information sheet and certificate of consent for participation and publication of data will be filled by the participants .

References

1 Kamper DG & Rymer WZ .Impairment of voluntary control of finger motion following stroke: role of inappropriate muscle coactivation. Muscle Nerve 2001;24:673–681

2 Lang CE & Schieber MH .Differential impairment of individuated fi nger movements in humans after damage to the motor cortex or the corticospinal tract. J Neurophysiol 2003;90:1160–1170

3 Colebatch J.G. & Gandevia S.C. The Distribution of Muscular Weakness in Upper Motor Neuron Lesions Affecting the Arm. Brain. 1989;112, 749-763.

4 Kamper DG, Harvey RL, Suresh S, et al. Relative contributions of neural mechanisms versus muscle mechanics in promoting fi nger extension defi cits following stroke. Muscle Nerve. 2003; 28:309–318

5 Li S, Latash ML&Yue GH.The effects of stroke and age on fi nger interaction in multi-fi nger force production tasks. Clin Neurophysiol Off J Int Fed Clin Neurophysiol . 2003;114:1646–1655

6 Heller A, Wade DT & Wood VA. Arm function after stroke: measurement and recovery over the fi rst three months. J Neurol Neurosurg Psychiatry . 1987;50:714–719

7 Sunderland A, Tinson D, Bradley L, etal .Arm function after stroke. An evaluation of grip strength as a measure of recovery and a prognostic indicator. J Neurol Neurosurg Psychiatry. 1989; 52:1267–1272

8 WHO. International Classification of Functioning, Disability and Health. Geneva: World Health Organization (WHO); 2001.

9 Jette AM. Toward a common language for function, disability, and health. Phys Ther. 2006;86:726–734.

10 Duncan P.W., Studenski S., Richards L.,

etal Randomized clinical trial of therapeutic exercise in subacute stroke. *Stroke. 2003;34 9, 2173-80* .

11 Arya, Kamal & Verma, etal. Meaningful Task-Specific Training (MTST) for Stroke Rehabilitation: A Randomized Controlled Trial. Topics in stroke rehabilitation. 2012; 19. 193-211.

12 Nijland R, Van Wegen EEH& Van der Krogt, H. Characterizing the protocol for early modified constraint-induced movement therapy in the EXPLICIT-stroke trial. Physiother Res Int. 2013;18:1-15.

13 Yozbatiran, Nuray & Der-Yeghiaian, etal. A Standardized Approach to Performing the Action Research Arm Test. Neurorehabilitation and neural repair. 2007;22. 78-90.

14 Aguiar L. T., Martins J. C., Lara E. M etal Dynamometry for the measurement of grip, pinch, and trunk muscles strength in subjects with subacute stroke: reliability and different number of trials. Brazilian journal of physical therapy.2016;20(5), 395–404.

15 Mulder, Marijn & Nijland etal .Stroke Impact Scale. Journal of physiotherapy. 2016 62. 2(2016):117

16 Nudo RJ, Plautz EJ, Frost SB. Role of adaptive plasticity in recovery of function after damage to motor cortex. Muscle & nerve. 2001 Aug 1; 24(8):1000±19.

17 Pomeroy VM, King L, Pollock A, Baily-Hallam A, Langhorne P. Electrostimulation for promoting recovery of movement or functional ability after stroke. Cochrane Database of Systematic Reviews. 2006(2).

18 Quandt F, Hummel FC. The influence of functional electrical stimulation on hand motor recovery in stroke patients: a review. Experimental & translational stroke medicine. 2014 Aug 21; 6(1):9.

19 Veerbeek JM, van Wegen E, van Peppen R, van der Wees PJ, Hendriks E, Rietberg M, et al. What is the evidence for physical therapy poststroke? A systematic review and meta-analysis. PloS one.2014;4; 9(2):e87987.

20 Langhorne P, Coupar F, Pollock A. Motor recovery after stroke: a systematic review. The Lancet Neurology.2009 Aug 31; 8(8):741±54.