

Effect of Electrical Stimulation (ES) Combined with Conventional Therapy on Spasticity, Function and Ambulation for Patients with Stroke: Protocol for a Randomized Control Trial

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ABSTRACT

Background: Spasticity is a motor symptom which is responsible for impairments as it decreases range of movement, postural abnormality, poor hygiene, inability to perform daily activities. Since the 1960s, electrical stimulation (FES) has been used to treat chronic hemiplegic patients. It is a physical therapeutic approach that improves spasticity by agonist muscle relaxation or antagonist muscle strengthening. This study aims to evaluate the effect of electrical stimulation along with conventional therapy and conventional therapy alone on spasticity, function and ambulation of the individuals suffering from Stroke. **Method and analysis:** The study will be a multicenter, Randomized Control Trial (RCT). Stroke survivors with spasticity in any limbs who will attend in the neurology unit of 24 selected rehabilitation centers including Center for the Rehabilitation of the Paralyzed (CRP) Savar and Mirpur Dhaka, Bangladesh from July 2022 to February 2023, will be considered as study population. Hospital based randomization processes will be employed. To receive either conventional intervention or EFS along with conventional, participants will be randomly assigned into [1:1] groups. Concealed allocation will be executed by computer generated randomization and will be done by another person who is not involved in the trial. Primary outcome spasticity will be evaluated by modified Asworth grading scale and modified Tardieu scale; function by Barthel Index and ambulation by 10-meter walk test. Secondary outcome upper extremity muscle strength will be evaluated by motricity index and lower limb function by lower extremity functional scale (LEFS). **Conclusion:** FES

with conventional therapy will add new knowledge to manage stroke patients. Reduction of spasticity and improvement of function will reduce the burden of stroke patients as well as their families. Hopefully this research will update the rehabilitation process of stroke patients in Bangladesh.

Key Words: Stroke, Electrical stimulation, Spasticity, Physical activity, functional independence.

INTRODUCTION

Spasticity is a motor symptom identified by increase of tonic stretch reflexes, as well as excessive tendon jerks which are velocity dependent and produce as a consequence of increased stretch reflex excitability and as a remarkable feature of upper motor neuron type of lesion [1]. It is responsible for impairments as it decreases range of movement, postural abnormality, poor hygiene, inability to perform daily activities, and also may cause pain. About 20%- 40% of stroke patients suffer from spasticity [2]. 3 follow-up studies stated that spasticity rate is 18% to 22% in individuals examined initially after stroke onset and at 3month, 1year, and 1.8 year after stroke, whereas another 2 studies of UK stated spasticity rate of 36% to 38% in individuals examined at 12-month after stroke. 1 study from Brazil stated the rate of spasticity is 25%, examined 12 months after stroke. This rate is 26% to 36% among the hemiplegic patients [3].

Since the 1960s, Functional electrical stimulation (FES) has been used to treat chronic hemiplegic patients [4]. Neuromuscular electrical stimulation (NMES) is a physical therapeutic approach that improves spasticity by agonist muscle relaxation or antagonist muscle strengthening. By promoting Renshaw cell recurrent inhibition, antagonist reciprocal inhibition and enhance cutaneous sensory stimuli, FES decreases the spasticity [5]. It has been stated that this approach reduces spasticity without causing muscle weakness or paralysis. Besides, it may enhance sensory inputs to the central nervous system (CNS), resulting in faster neural plasticity and motor learning. Electrical stimulation has been reported to improve muscle tonicity by minimizing the stretch reflex, producing lower spasticity and a wider range of movements, as well as preventing soft tissue tightness and contracture. Despite the fact that various studies have been undertaken, there are still conflicting reports about the effect of electrical stimulation on spasticity reduction [6].

In Bangladesh, Center for the Rehabilitation of the Paralyzed (CRP) has the facility to rehabilitate the people living with Stroke for a prolonged period of time. Moreover, there is limited use of Functional electrical stimulation (FES). Although the device is supported by some evidence, the study has not yet been done in Bangladesh.

Objectives

The primary objectives are to,

- 1) Evaluate the effect of electrical stimulation along with conventional therapy and conventional therapy alone on spasticity among the individuals suffering from Stroke.
- 2) Evaluate the effect of electrical stimulation along with conventional therapy and conventional therapy alone on function among the individuals suffering from Stroke.
- 3) Evaluate the effect of electrical stimulation along with conventional therapy and conventional therapy alone on ambulation among the individuals suffering from Stroke.

The secondary objectives are to,

- 1) Assess the effect of electrical stimulation along with conventional therapy and conventional therapy alone on upper extremity strength among the individuals suffering from Stroke.
- 2) Assess the effect of electrical stimulation along with conventional therapy and conventional therapy alone on lower extremity functions among the individuals suffering from Stroke.

Hypothesis for the primary objectives/outcome

- 1) Stroke patients who will receive electrical stimulation along with conventional therapy will achieve more improvement in spasticity when we will compare them with conventional therapy alone group.
- 2) Stroke patients who will receive electrical stimulation along with conventional therapy will achieve more improvement in function when we will compare them with conventional therapy alone group.
- 3) Stroke patients who will receive electrical stimulation along with conventional therapy will achieve more improvement in ambulation when we will compare them with conventional therapy alone group.

METHODOLOGY

Study design

The study will be a multicenter, Randomized Control Trial (RCT). The control group will receive only usual care that is conventional therapy and the intervention group will receive the FES along with conventional therapy as per the stated intervention protocol.

Study site and participants

Stroke survivors with spasticity in any limbs who will attend in the neurology unit of 24 selected rehabilitation centers including Center for the Rehabilitation of the Paralyzed (CRP) Savar and Mirpur Dhaka, Bangladesh from July 2022 to February 2023, will be considered as study population. Here participants will come for rehabilitation service. From the population based on criteria set by the researchers, study samples will be selected. Participants to be included in this study should have following criteria-(1) more than 18 years; (2) hemiplegic for longer than 6months; (3) both male and female patients; spasticity present at (anyone or multiple) Elbow (flexors and extensors), wrist (flexors and extensors) and knee (flexors and extensors), ankle (dorsiflexors and plantar flexors) of hemiplegic side;(4) want to participate voluntarily. On the other hand, participants will be excluded if- (1) they have sensory deficit in the target area; (2) contracture that could restrict movement; (3) taking medication to reduce spasticity; (4) cognitive impairment; (5) unwilling to participate.

Recruitment and Randomization of the participants

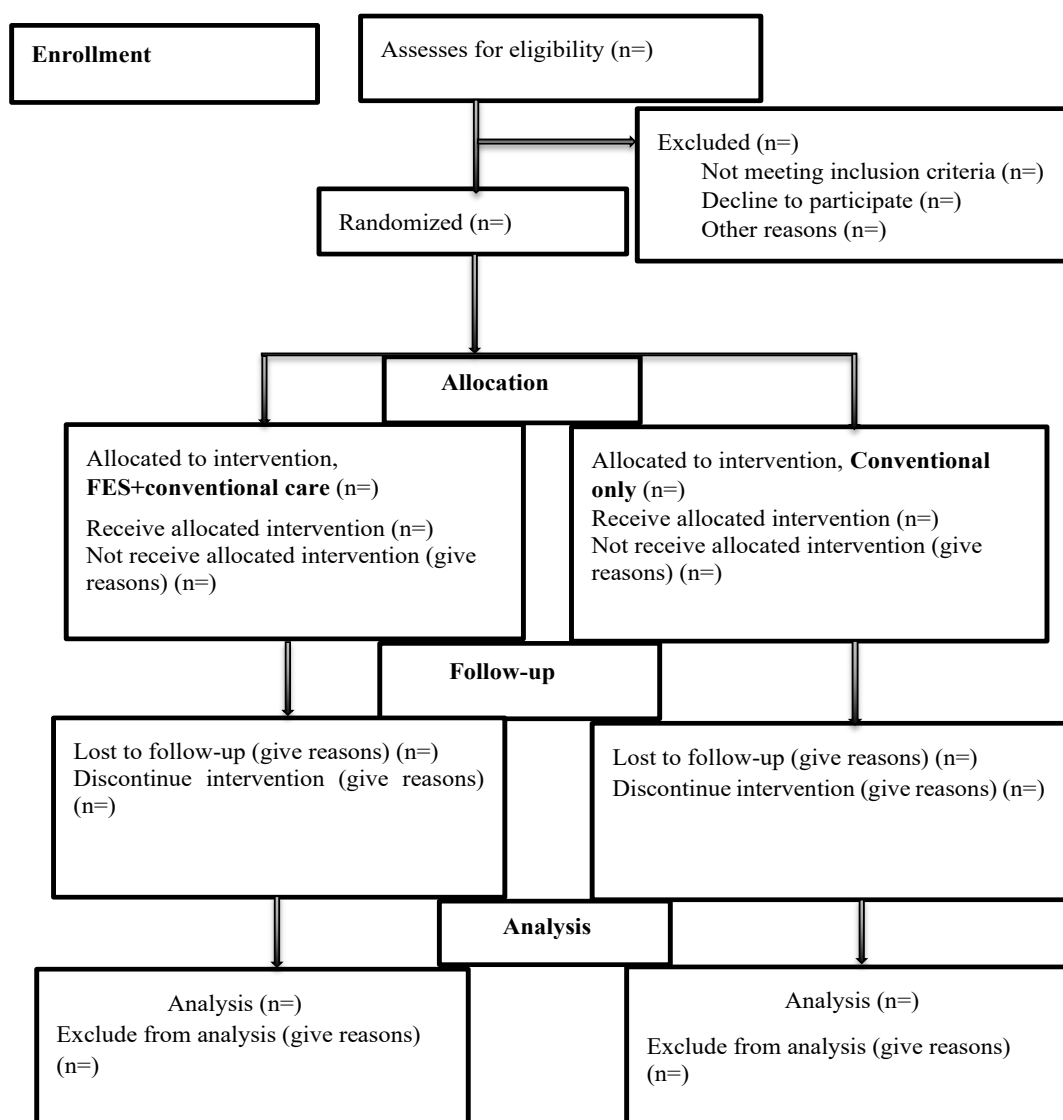
Hospital based randomization processes will be employed. Within the determined time frame, all the stroke patients attending in 24 rehabilitation centers will undergo screening and those who fulfill the eligibility criteria will be recruited for trial. To receive either conventional intervention or EFS along with conventional, participants will be randomly assigned into [1:1] groups. Concealed allocation will be executed by computer generated randomization and will be done by another person who is not involved in the trial. Written informed consent will seek

from the patients, their family members or near relatives. Participants can withdraw during trial or unavailable during follow up, all information will be noted in detail.

Procedure

A record book will be maintained for the patients who will come for rehabilitation service and if the patients meet the criteria, will be invited for participation in the trial. A written informed consent form will provide and inform the patients in detail about the study. If they give consent, the assessor will take the baseline information including sociodemographic and disease related information, and score of spasticity, function, and ambulation. Then the randomization will do. The baseline, post-test and follow up, all assessment will be completed by a blind assessor. Baseline assessment will be conducted before randomization, post-test after 1month of intervention and follow-up assessment will be conducted after 3month. Participants screening for data analysis of trials will be started by following modified CONSORT (Consolidated Standards of Reporting trials) for non-pharmacological trials (**table- 1**).

Table-1: CONSORT Flow Diagram



Interventions

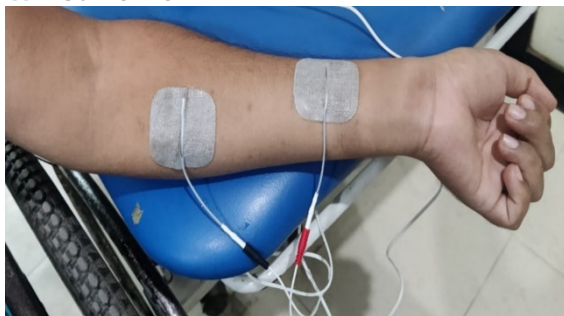
Conventional care

Both groups will receive usual care at the rehabilitation center. Expert physiotherapists will provide the standard physiotherapy treatment but those treatments are not protocolized. Treatment will includes positioning, stabilization of the pelvic girdle, knees and shoulder girdle, sensory stimulation of U/L and L/L, proprioceptive exercise of U/L and L/L, transitional movement practice, body schema practice, scapular setting exercise, proximal stability exercise, selective movement practice, midline orientation exercise, trunk mobilization, pelvic girdle mobilization, shoulder girdle mobilization, hand and foot mobilization, selective movement practice of U/L and L/L, functional activity training, core strengthening exercises, static sitting and standing balance practice, dynamic sitting and standing balance practice, stepping practice , gait reeducation, stairs up and down practice, Gym activities like cycling, static runner , treadmill etc. Total treatment session will be 45 minutes and will receive 3session of treatment/week. Total procedure will be noted in detail.

FES with conventional therapy group

A FES device (Neurotic Rehab) with 2 channels and 4 surface electrodes producing low-frequency currents will be used for targeted muscle groups (**figure-1**). Stimulation parameters will be set as: frequency -50HZ, pulse width- 300mS, on: off- 10:10 seconds, ramp up and down time- 2 seconds, amplitude- as tolerable by patient (can deliver up to 100mA). Repetition of movement- 20 repetition for each muscle group. 5-to-5-centimeter electrodes will be used for small muscle groups and 7-to-13-centimeter electrodes will be used for large muscle groups. Treatment will provide for 1times in a day, total 3session/ week.

Wrist flexion



Wrist Extension



Elbow Flexor



Elbow Extensor



Knee Flexion**Knee Extension****Ankle Dorsiflexor****Ankle Plantar flexor**

Figure-1: Electrode placement at different muscle group

Blinding

Blinding of the participants and treatment provider is not possible therefore, assessors will be blinded in this study. They will not be informed about group allocations. Participants will also be requested, not to discuss their intervention with the assessor.

OUTCOME MEASUREMENT

All outcomes will be measured at baseline, 1 month after intervention, follow up after 3month. Baseline data will include patients' socio-demographics like age, gender, occupation, BMI; health related information e.g., types of strokes, affected side and history of comorbidities etc. **Table- 2** shows the outcomes measurement plan including the time of measurement.

Table-2: Outcome measurement plan

	Baseline	Posttest after 1 month	Follow up after 3month
Socio-demographic information	√	√	√
Disease related information	√	√	√
Spasticity measurement Modified Ashworth grading scale Modified Tardieu scale	√	√	√
Function measurement Barthel Index	√	√	√
Ambulation 10-meter walk test	√	√	√
Upper extremity strength Motricity index	√	√	√
Lower extremity function Lower extremity functional scale	√	√	√

PRIMARY OUTCOMES MEASUREMENT TOOLS:

Spasticity

1. *Modified Ashworth Scale:* Patient will undergo spasticity measurement by modified Ashworth scale. This is the most used scale for spasticity measurement and it enables measuring spasticity by a 6-point (0-5) rating scale. To obtain the score examiner needs to move a limb through its full range and note the amount of resistance perceived by their hand. Minimum score of this scale is '0= No increase in muscle tone" and maximum score is "5= affected limb is rigid in flexion and extension" [7,8].
2. *Modified Tardieu Scale:* The Modified Tardieu Scale evaluates spasticity based on 3 types of velocities- [i] slow, [ii] normal and [iii] fast and by the snap angle. While muscle contraction is generated by movement velocity and muscular resistance, this scale has high sensitivity to measure the changes after interventions [1].

Barthel Index (BI)

The Barthel Index scale used to assess the performance of daily living functions. 10 daily living functions and movement are included. Lower the number indicates a reduced ability of independent function, and greater the number indicates the higher ability of independent function. Functions include- eating, toileting, taking bath, put in and out of dress, getting on and off a toilet, maintenance of bladder, maintenance of bowel, transferring from wheelchair to bed and bed to wheelchair, walking on smooth surface (or propelling a wheelchair if cannot walk) and climbing up and down stairs [9].

10-meter walk test

Performance of ambulation of the patients will be measured by a 10-meter walk test. This test used to examine the walking speed in m/sec (meter per second) in a short period. To find out the result patients will be instructed to walk 10 meters without assistance, but the time measured for the middle 6 meters. 1st 2-meter and last 2-meter for preparation of acceleration and deceleration. If unable to walk without support, assistive devices can be used, but must be kept consistent and noted. Two trials are administered at the patient's comfortable walking speed, followed by 2 trials at his/ her fast-walking speed. First 2 trials are instructed to walk at

a comfortable speed for the patients, then 2 trials at fast speed. Then the average score of 2 trials for each speed is noted in m/s. For the stroke patients test-retest reliability (ICC = 0.95 to 0.99) and interrater reliability (ICC = 0.87 to 0.88) of this scale were found as excellent [10].

SECONDARY OUTCOME MEASUREMENT TOOLS

Motricity Index (MI)

Upper extremity strength will be measured by this scale. It is a manual muscle testing score for shoulder abduction, elbow flexion and pinch grip. Total scores are converted to a total force producing score for every side, which ranges from no strength= 0 to full strength =10 [11]. Upper extremity MI for subacute and chronic stroke has excellent interrater reliability ($r_s=.88$, $p<.0001$) and excellent intra-rater reliability (ICC=.93, 95% CI=.84, $p<.0001$) [12].

Lower Extremity functional Scale (LEFS)

The Lower Extremity Functional Scale (LEFS) aims to measure the lower extremity functions. Patients' preliminary function, continuing progression, and consequence of intervention can be assessed. The LEFS is a subjective assessment tool. Patients are asked about twenty daily activities. Answers are labeled as 1= extreme difficulty or unable to perform, 2= quite a bit of difficulty, 3= moderate difficulty, 4= a little bit of difficulty, 5= no difficulty. The highest probable score is 80, which indicates the patient's functional level is very high. The lowest probable score is 0, which indicates patients' functional level is very low [13].

Statistics

Sample size calculation will not be done as the determined sample frame will be a hospital-based randomization. Data will be analyzed by SPSS 22 version and Microsoft Excel 13. The statistical test will select according to the nature of the Data according to Kolmogorov-Smirnov test and Shapiro wilk test. For parametric data the pretest to posttest between group analyses will be conducted through independent t test and within group through paired sample t test. The pretest to follow up one way ANOVA will be performed and subsequent post-hoc test will be performed. For non-parametric data the non-parametric alternative tests will be performed. The level of significance is set as alpha value less than .05, for post-hoc Bonferroni correction will be made.

Ethical issues

The trial obtained ethical permission from Institute of Physiotherapy Rehabilitation and Research of Bangladesh Physiotherapy Association (BPA) [IPRR/IRB/24/02/2022/089]. Also, the trial is registered to Clinical Trial Registry India, the primary trial site of World Health Organization [CTRI/2022/03/041409]. The researcher will follow the Helsinki declaration as per ethical guidelines. The participants participation will be voluntary and they will have the right to withdraw from the trial anytime during the trial. The participants will be assured that participation or withdrawal from the study will not make any change to their regular treatment process.

Safety measure

It is expected that the stated protocol will be risk free, but if any unexpected event occurs during or after intervention this will be noted and informed to the principal investigator. Before starting treatment, patients should be informed that if they feel pain, skin irritation or any kind

of discomfort they must report it to their physiotherapist. Physiotherapists should also be conscious about equipment. Before intervention equipment should be checked properly.

RESULTS

This trial will evaluate the effect of electrical stimulation along with conventional therapy vs conventional therapy alone on spasticity, function and ambulation of stroke patients. Besides the study will determine the effect of stated protocol on upper extremity strength and lower limb function of stroke patients. Although it is difficult to say which group will show better results, it is expected that the experimental group will show better results than the control group.

DISCUSSION

Spasticity affects more than one out of 4 patients [1]. It causes limitation of the functional activities of the patient. This study will help to explore the effect of electrical stimulation along with the conventional practice on spasticity management of different rehabilitation of Bangladesh. Minimization of spasticity will hopefully improve the function and ambulation of the stroke patients. Overall, from the findings conventional physiotherapy protocol of stroke will help to ensure evidence-based practice guidelines in Bangladesh and the FES with conventional protocol will explore new dimensions of treatment in Bangladesh. Besides this study will create a future scope of study about FES for stroke patients in Bangladesh. Researchers will get a guideline about appropriate sample size, outcome measurement as well as overall study design.

CONCLUSION

FES with conventional therapy will add new knowledge to manage stroke patients. Reduction of spasticity and improvement of function will reduce the burden of stroke patients as well as their families. Hopefully this research will update the rehabilitation process of stroke patients in Bangladesh.

References

- [1]. Thibaut A, Chatelle C, Ziegler E, Bruno MA, Laureys S, Gosseries O. Spasticity after stroke: physiology, assessment and treatment. *Brain injury*. 2013 Sep 1;27(10):1093-105.
- [2]. Sommerfeld DK, Gripenstedt U, Welmer AK. Spasticity after stroke: an overview of prevalence, test instruments, and treatments. *American Journal of Physical Medicine & Rehabilitation*. 2012 Sep 1;91(9):814-20.
- [3]. Schinwelski M, Sławek J. Prevalence of spasticity following stroke and its impact on quality of life with emphasis on disability in activities of daily living. Systematic review. *Neurologia i neurochirurgia polska*. 2010;44(4):404-11.
- [4]. Yan T, Hui-Chan CW, Li LS. Functional electrical stimulation improves motor recovery of the lower extremity and walking ability of subjects with first acute stroke: a randomized placebo-controlled trial. *Stroke*. 2005 Jan 1;36(1):80-5.
- [5]. Sahin N, Ugurlu H, Albayrak I. The efficacy of electrical stimulation in reducing the post-stroke spasticity: a randomized controlled study. *Disability and rehabilitation*. 2012 Jan 1;34(2):151-6.
- [6]. Bakhtiary AH, Fatemy E. Does electrical stimulation reduce spasticity after stroke? A randomized controlled study. *Clinical rehabilitation*. 2008 May;22(5):418-25.
- [7]. Harb A, Kishner S. Modified ashworth scale. InStatPearls [Internet] 2021 May 9. StatPearls Publishing.

- [8]. Rekand T. Clinical assessment and management of spasticity: a review. *Acta neurologica scandinavica*. 2010 July; 122:62-63.
- [9]. Barthel Index [Internet]. Shirley Ryan Ability Lab. 2022 [cited 19 June 2022]. Available from: <https://www.sralab.org/rehabilitation-measures/barthel-index>.
- [10]. 10 Meter Walk Test [Internet]. Shirley Ryan Ability Lab. 2022 [cited 19 June 2022]. Available from: <https://www.sralab.org/rehabilitation-measures/10-meter-walk-test>.
- [11]. Malmut L, Lin C, Srdanovic N, Kocherginsky M, Harvey RL, Prabhakaran S. Arm subscore of motricity index to predict recovery of upper limb dexterity in patients with acute ischemic stroke. *American Journal of Physical Medicine & Rehabilitation*. 2020 Apr 1;99(4):300-4.
- [12]. Motricity Index [Internet]. Shirley Ryan Ability Lab. 2022 [cited 19 June 2022]. Available from: <https://www.sralab.org/rehabilitation-measures/motricity-index>.
- [13]. Verheijde JL, White F, Tompkins J, Dahl P, Hentz JG, Lebec MT, Cornwall M. Reliability, validity, and sensitivity to change of the lower extremity functional scale in individuals affected by stroke. *PM&R*. 2013 Dec 1;5(12):1019-25.