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PROTOCOL FOR BIHEMISPERIC TRANSCRANIAL DIRECT CURRENT STIMULATION (tDCS) AND BILATERAL ARM TRAINING ON NEUROLOGICAL UPPER LIMB IMPAIRMENTS

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Abstract: Transcranial Direct Current Stimulation (tDCS) is a non-invasive brain stimulation that can improve the limb's motor function by remote modifications in the central motor system. Bilateral Arm training (BAT) involves use of the affected arm which is in association with the unaffected arm that initiate interlimb coupling, which mitigates interhemispheric inhibition and in turn helps improving affected limb function. The current paper presents the protocol for conducting research into the efficacy of Transcranial Direct current stimulation and Bilateral Arm Training on neurological upper limb impairments. A single blind randomized clinical trial will be conducted involving Transcranial Direct current stimulation and Bilateral Arm Training on 20 individuals with neurological upper limb impairments. The group A intervention consists of Bihemispheric stimulation of 1 mA for 20 minutes while group B will receive Bilateral arm training along with convention therapy in both the groups for a total duration of 50 minutes. Participants of the assigned group will receive 10 sessions of treatment over 2 weeks. Outcomes used will be subjective Pre and post-treatment assessments will be done using Wolf Motor Function Test (WMFT) and Fugyl Meyer assessment-upper extremity (FMA-UE).

Index Terms **- tDCS, stroke, bilateral arm training, neurological upper limb impairments.**

I. Introduction

A prolonged arm disability is linked to a reduced quality of life and a decreased sense of well-being.[1] Stroke is a significant global cause of mortality and disability, impacting both developed countries and, to a greater extent, low- and middle-income nations (LMICs). Stroke is now the fifth most common cause of disability and the fourth main cause of death in India.[2] Following a stroke, upper-limb motor dysfunction plays a major role in the decline of independence in daily tasks. 80% of individuals with stroke have impairment in their upper limb motor function, and 50 to 60% of those who survive still experience problem after 6 months. Different strategies for measuring motor function reflect the fact that impairments in movement can be caused by only one or more of the following, decreased speed, coordination, strength and range of motion.[2] Functional constraints in the use of the affected upper limb following a stroke arise from impairments in that limb. In stroke mimics, neurological symptoms tend to be less distinct and may not align with recognized stroke syndromes(15). It is essential to assess these impairments in terms of their functional consequences. The three primary functional problems are learned non-use, learned bad use and forgetting.[4] Even the most fundamental everyday tasks, like eating, washing, dressing, and so on, require good upper limb control. The results of rehabilitation frequently result in partial motor recovery, and more than 60% of patients are unable to do functional tasks with their paralyzed hands.[3] Furthermore, it is believed that significant paresis at four weeks is a poor predictor of motor recovery, suggesting that these patients will likely face significant challenges in their future performing activities of daily living.[6] These challenges have a direct impact on quality of life. Thus, it is essential to pay attention to improvements in upper limb function after a stroke in order to enhance everyday activities, enhance quality of life, and optimize recovery. [7,8] To carry out activities including eating, dressing, and drinking, bilateral upper limb movement is essential. Since most daily tasks require using both arms, we included bilateral arm training (BAT) in this protocol. This will involve using the affected arm in conjunction with the unaffected arm, allowing for goal-directed, active use of the limb that can lead to functional gains. Interlimb coupling, which mitigates interhemispheric inhibition and helps to engage the damaged hemisphere and improve affected limb motor control, is a feature of this technique.[8] By remotely altering the cortical motor system, transcranial direct current stimulation (tDCS) a non-invasive brain stimulation technique, can improve the motor function of the injured limb.[10] Motor evoked potentials amplitude is reduced by cathodal stimulation and increased by anodal stimulation.[11] As there is interhemispheric inhibition from the non-affected hemisphere to the affected hemisphere. Hence, we hypothesize that bihemispheric tDCS may help in modulating the interhemispheric inhibition. The anode will be placed over the lesioned hemisphere M1 and cathode on the contralesional hemisphere M1. As both of these interventions work to activate the affected hemisphere, and reduce inhibition from the unaffected hemisphere, the study compares the effects of bilateral arm training and tDCS on motor function in order to determine which intervention is more effective in treating upper limb motor deficits. Using the Wolf motor function test (WMFT) and the Fugyl Meyer Motor Assessment-Upper Extremity (FMA-UE), the study aims to assess and observe the impact of bilateral arm training and bihemisphere tDCS on neurological upper limb motor deficits.

II. STUDY AIMS AND OBJECTIVES

Aim: To see the effect of Bihemispeheric Transcranial Direct Current Stimulation and Bilateral Arm Training in neurological upper limb motor Impairments.
Objectives: To evaluate and see the effect of Bihemispeheric Transcranial Direct Current Stimulation and Bilateral Arm Training in neurological upper limb motor impairments using Wolf motor function test (WMFT) and Fugyl Meyer Motor Assessment-Upper Extremity (FMA-UE)

III. MATERIALS AND METHOD

The proposed Clinical trial CTRI/2024/01/061375 will be a single blinded randomized clinical trial of bihemispheric tDCS and Bilateral arm training to examine their effect on neurological upper limb impairments.

3.1 Hypotheses

We hypothesise that there will be difference between the effect of tDCS and Bilateral Arm Training in upper extremity motor functions in Neurological Upper limb Motor Impairments.

3.2 Participants

3.2.1 Sampling

Participants will be recruited from Tertiary care Hospital Belagavi, Karnataka. Sample size was determined using the technique of estimating sample size for Paired "t" test. The sample calculated is 20. Participants who meet the inclusion criteria and will be asked to fill out the informed consent form to confirm their participation in the study. Participants will be randomly allocated one of the two treatment groups by envelope method. Once they are included in the study their pre-intervention assessment will be taken and following 2 weeks of intervention their post-intervention assessment will be taken by principal investigator.

3.2.2 Inclusion criteria

- Participants willing to participate
- Participants of age group 21-75 years of all genders
- Participants with history of traumatic brain injury and cerebral vascular accident having upper limb motor impairments
- Hemodynamically stable condition
- Unilateral motor impairment
- Should be able to follow the command
- Spasticity in affected upper limb ranging from grade 1 to grade 3 as per Modified Ashworth Scale

3.3.3 Exclusion Criteria

- Aphasia
- Epilepsy
- Intracranial metallic Implants or any surgeries over cranium
- Psychiatric illness
- Peripheral nerve injuries
- Musculoskeletal impairments

3.3.4 Procedure:

Pre intervention assessment of the participants will be done using Wolf motor function test (WMFT) and Fugyl-Meyer motor assessment-upper extremity FMA-UE. The interventions in both the group will be given by the principal investigator. After giving information about protocol Group A subjects will be given Bihemisperic tDCS in following manner. Before placement the electrodes will be soaked with sodium chloride solution. The electrodes will be placed on C3-C4 point following the International 10-20 EEG electrode system. The anode will be positioned at the ipsilesional area and cathode will be positioned at the contra lesional area, a current of 1mA will be delivered for twenty minutes and thirty minutes of conventional exercises will be delivered.

Group B subjects will be given Bilateral Arm training (BAT) in following way. This exercise will include almost all Activities of daily living such as holding a bottle with one hand and opening it with other hand and then pouring water from that bottle to a the glass and drinking it with the other hand, folding laundry, pushing a chair with both hands, placing two similar objects, organizing a drawer, wringing of clothes, tearing sheets of paper, folding and unfolding sheets of paper using both hands. All these activities will done for a total time of 30 minutes. Followed by 20 minutes of conventional treatment.

Since no serious side effects have been documented with low-current techniques like the ones suggested in this study, the procedure is regarded as extremely low risk. Localized scalp itching or tingling at the electrode placement site are possible adverse effects of low-current tDCS. With infrequent headaches or exhaustion. If any of these side effects occur, the participant will be monitored and will be referred for assessment to a medical practitioner. Discontinuation and/or withdrawal from the study will be recorded in the study database.(16)

3.3.5 Statistical Analysis

The collected data will be summarized by using the Descriptive Statistics: frequency, percentage; mean and S.D. To find the effectiveness of interventions: Bi Hemispheric Trans cranial Direct Current Stimulation, Bilateral Arm Training; the Paired "t" test will be used. If data are not following normal distribution, the Wilcoxon signed rank test will be used to find the effectiveness. Between groups comparisons (Bi Hemispheric Trans cranial Direct Current Stimulation vs. Bilateral Arm Training) will be analyzed by using Independent sample "t" test. If data are not following normal distribution, the Mann Whitney "U" test will be used for between group comparisons. The Chi square or Likelihood ratio test will be used to compare difference in proportions. The p value < 0.05 will be considered as significant.

IV. DISCUSSION

This randomized clinical trial aims to investigate the efficacy of bihemispheric transcranial direct current stimulation (tDCS) and bilateral arm training (BAT) on upper limb motor function in individuals with neurological impairments. Upper limb dysfunction remains a significant contributor to long-term disability following stroke and traumatic brain injury, affecting independence and quality of life(2). Bihemispheric tDCS, by enhancing excitability in the ipsilesional hemisphere and concurrently inhibiting the contralesional hemisphere, has demonstrated potential in restoring interhemispheric balance and promoting motor recovery

[9]. Evidence suggests that tDCS, when combined with task-specific training, may further enhance neuroplasticity and functional outcomes [12].

Bilateral arm training utilizes symmetrical and coordinated movements to facilitate interlimb coupling, activating homologous cortical regions and promoting motor relearning [11,13]. Studies have shown that BAT can significantly improve upper limb function and activities of daily living in post-stroke patients [14]. The synergistic application of neuromodulation techniques like tDCS with functional training paradigms such as BAT could optimize motor recovery by simultaneously targeting cortical excitability and behavioral motor learning mechanisms.

Outcome measures including the Wolf Motor Function Test and the Fugl-Meyer Assessment are selected due to their robust psychometric properties and clinical relevance [9,10]. Results from this trial may provide valuable insights for developing evidence-based rehabilitation strategies aimed at maximizing upper limb recovery. Furthermore, the findings could contribute to expanding the therapeutic use of non-invasive brain stimulation in neurorehabilitation practice.

Conflicts of interests: Authors declare no conflict of interest

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