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Efficacy of Electrical Stimulation (ES) on Upper Limb Neurological and Functional recovery in Patients with Spinal Cord Injury: Protocol for a Randomised Controlled Trial

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Md Obaidul Haque¹, Hassan M. Al- Emran²

¹Department of Physiotherapy, BHPI, CRP, Savar, Dhaka, Bangladesh;

²Associate Professor & Chairman, Department of Biomedical Engineering, Jashore University of Science and Technology (JUST), Jashore-7408



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We use this protocol and it's working

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Abstract

Background: Spinal cord injury (SCI) causes physical disability including a deterioration of upper limb function that have a considerable impact on an individual's functional status and independence. Electrical stimulation (ES) is the use of low-energy electrical pulses to induce muscular contraction, particularly in SCI patients. This study will determine the ES efficacy for upper limb functional and neurological improvement in SCI patients.

Methods: Forty traumatic tetraplegic (TT) SCI patients will be recruited to this single blind clinical trial and will be randomly allocated to intervention and control group. The intervention group will receive a one-hour treatment that includes ES for 30 minutes and rest of the usual therapy for 4 weeks. The primary outcomes are Capabilities of Upper Extremity (CUE) Instruments, ASIA impairment scale (ASIA motor scores, ASIA sensory scores and neurological level). The secondary outcomes include Modified Ashworth Scale (MAS) and Manual muscle testing (MMT). ES will be placed on the extensor and flexor group of muscles of the wrist and elbow. Baseline will be performed at the commencement of participant recruitment in the trial and post-test will be performed after ten sessions and consequently twenty sessions of the intervention. The recruitment of participants started on October 1st, 2022, and the trial will be continued until the completion of recruitment of forty participants.

Analysis: Data will be analysed based on the nature of data. Categorical data will be displayed using frequencies and corresponding percentages, whereas continuous data will be displayed using descriptive statistics. Intention-to-treat analyses will be carried out.

Ethics and dissemination: The study has been evaluated by the Ethics Committee of Centre for the Rehabilitation of the Paralysed and Jashore University of Science and Technology, Jashore, Bangladesh. All participants will provide consent. The protocol will follow the SPIRIT (Standard Protocol Items for Randomized Trials) statement. All protocol requirements will be followed during the duration of the trial. Findings will be disseminated in peer-reviewed publications and presented at academic, national and international conferences.

Trial registration number: [CTRI/2021/11/038271].

