OFFICIAL STUDY TITLE:

Transcutaneous Electrical Stimulation for Spasticity in Patients with Primary Lateral Sclerosis

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Study Protocol

Six participants with a confirmed diagnosis of PLS were enrolled to receive the tSCS intervention, which consisted of a single 30-minute tSCS session. Participants were recruited as a convenience sample during their multidisciplinary clinic visits at a university-based ALS center or via ClinicalTrials.gov (NCT06012110). Recruitment occurred over a one-year period from September 2023 to August 2024. Inclusion criteria included: (1) confirmed diagnosis of definite PLS by a neurologist specializing in neuromuscular disorders using the consensus diagnostic criteria for PLS,[1] (2) ambulatory with or without an assistive device or orthotic, 3) self-reported spasticity in the lower limbs, and 4) no prior history of tSCS treatment. Exclusion criteria included: (1) history of cancer in the lumbar or thoracic spine, (2) history of past surgery with hardware in the lumbar or thoracic spine, (3) acute lower back pathology, (4) current pregnancy, (5) history of implantable cardiac device (excluding loop recorder), (6) diagnosis of significant cognitive impairment, (7) history of seizures or diagnosis of epilepsy, (8) open wound at the area of electrode placement, and (9) complete loss of sensation at the area of electrode placement. This study was approved by the Institutional Review Board at Nova Southeastern University (2023-219-NSU) and met the institutional Health Insurance Portability and Accountability Act policy requirements for disclosure of protected health information. All participants provided written informed consent.

Study participation consisted of one in-person clinic visit and one 24-hour post treatment telephone interview. All outcome measures were assessed immediately pre- and post-intervention by the principal investigator (PI, KC) a licensed Doctor of Physical Therapy (DPT) with board certification as a Neurologic Clinical Specialist (NCS). Medications, physical activity and orthotic use were documented but unrestricted; however, no participants elected to use orthotics.

INTERVENTION

Two self-adhesive surface electrodes (90mm x 50mm) were positioned adjacent to the T11/T12 spinous processes at a distance greater than or equal to one inch apart, and a second pair of self-adhesive surface electrodes (80mm x 130mm each) were placed para-umbilically on the lower abdomen at a distance greater than or equal to one inch apart. Each set of electrodes, one set on the abdomen (ventral surface) and the other set on the back (dorsal surface), were connected so that each set effectively functioned as a single, larger electrode, one on each surface as previously described. Participants were then positioned supine with one pillow placed under their knees for comfort.

tSCS was administered by the PI using a current-controlled TENS device (InTENSity Select Combo II, Compass Health Brands Corp., Middleburg Heights, OH) that delivered charge-balanced, symmetrical biphasic rectangular pulses. The paraspinal electrodes acted as anodes in the first (positive) phase and cathodes in the second (negative, stimulating) phase.

The TENS unit was initially set to a frequency of 1 Hz and pulse duration of 400 μseconds. The frequency of 1 Hz was used to verify electrode placement by applying stimulation to induce mild posterior root-muscle reflexes (PRMR) in the L2–S2 innervated muscles, including the rectus femoris, biceps femoris, tibialis anterior, and triceps surae, bilaterally. The presence of these PRMR was confirmed through observation and palpation of muscle contractions or tendon responses, as prior studies have shown that their activation reflects the direct stimulation of sensory afferent fibers within the dorsal root of the spinal cord.[7,8] Amplitude was increased from 0 mA until reflexive muscle contractions or observable tendon responses were noted at the Patellar and Achilles tendons on both sides. Participants remained supine during this process.

Following PRMR identification, the frequency was increased to 50Hz while the pulse width remained at 400 μseconds to deliver the therapeutic stimulation, consistent with published parameters showing these settings activate synaptic inputs to inhibitory circuits, which may promote functional modulation through afferent pathway activation.[2-4,6,9] A threshold of < 90% of the PRMR response was used in prior studies to avoid direct motor neuron activation while ensuring activation of proprioceptive Ia afferent fibers. Accordingly, stimulation amplitudes were increased from 0 mA to each participant's tolerance level, while remaining below 90% of the lowest PRM threshold to avoid eliciting the PRMR.

Participants remained supine while undergoing a 30-minute tSCS session. This 30-minute duration reflects the therapeutic stimulation period only and does not include setup, PRM identification, or electrode and device removal. The PI remained with each participant throughout the intervention, instructing them to report any discomfort and offering the option to discontinue treatment if necessary. At the end of the intervention, the TENS unit was powered off, the electrodes were removed, and post-intervention testing was conducted.

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