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Neuromuscular Electrical Stimulation and Mobility in Multiple sclerosis

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Study Protocol

Written Description of the Clinical Study

The study examined the efficacy of electrical-stimulation treatment at reducing disability status and improving mobility in persons with mild-to-moderate levels of disability due to multiple sclerosis (MS).

Objective

The purpose of this study was to investigate the capacity of a 6-week treatment with neuromuscular electrical stimulation (NMES) to improve walking in individuals whose mobility has been compromised by multiple sclerosis.

Design

In a double-blinded, randomized design, participants were assigned to one of two groups: narrow-pulse group (n = 13; 54.9 ± 4.5 yrs) or wide-pulse group (n = 14; 50.4 ± 9.0 yrs). Participants and evaluators were blinded to the type of intervention. Each participant attended 3 evaluation sessions and 18 NMES treatment sessions distributed over 6 wks. Each evaluation session comprised 2 days of testing. Evaluation sessions were performed before (Week 0) beginning the 6-wk treatment, within 1 wk after finishing the treatment (Week 7), and approximately 4 wks after completing the treatment (Week 11).

Methods

On the first day of the evaluation sessions, participants performed the two walking tests (25-ft walk and 6-min walk), a manual dexterity test (grooved pegboard), completed three questionnaires, and were instructed on how to measure daily levels of physical activity. Maximal walking speed was measured as the time it took to walk 25 ft as quickly as possible from a stationary start. The average of two trials was used as the measure of maximal walking speed. Walking endurance was characterized as the distance walked in 6-min around a 140-m track. Participants were encouraged to walk briskly, and the distance covered at 1, 2, 4, and 6 min was recorded.

The grooved pegboard test, the three questionnaires, and the daily levels of physical activity were used to assess disability status. Manual dexterity was quantified as the time taken to complete the grooved pegboard test, which required participants to place 25 pegs into holes on a pegboard as quickly as possible. The questionnaires were the Patient Determined Disease Steps (PDDS), Modified Fatigue Impact Scale (MFIS), and MS Walking Scale-12 (MSWS-12). Physical activity was measured with the GENEActive accelerometer (Activinsights Limited, Cambridge, UK) for 7 consecutive days beginning on the second day of evaluations and quantified during at least 24-hr days during that period. Participants were asked to wear the waterproof sensors all the time, but were permitted to remove it at night if it disturbed their sleep. The monitor was worn on the same wrist and the data were sampled at 30 Hz. Custom software (Matlab R2015a, Mathworks, Natick, MA) was used to filter the signals (band pass of 0.2 to 15 Hz), calculate an average gravity-subtracted signal vector magnitude, quantify activity counts per second, and identify non-wear times (> 10 hrs). Based on norms established for healthy adults, maximal activity category cut-points were set for *Sedentary* (1.4), *Light* (4.0), and *Moderate*

(11.3) accelerations per second to estimate the proportion of daily time spent performing different levels of physical activity. The main reason for including this assessment was to quantify the potential negative impact of the intervention on daily levels of physical activity.

On the second day of the evaluation sessions, muscle strength and force steadiness were measured. Subjects lay in a supine position and a strap was placed around the forefoot and connected to a strain-gauge transducer (MLP-300, Transducer Techniques, Tenecula, CA). The measured force was sampled at 2 kHz (Power 1401, Cambridge Electronic Design, Cambridge, UK) and displayed on a monitor that was placed ~1 m in front of the subject. Muscle strength was quantified as the peak torque (N•m) achieved by the dorsiflexor and plantar flexor muscles of each leg when participants gradually increased muscle torque up to maximum and sustained it briefly. Participants performed up to 5 trials until two maximal values were within 10% of each other; the greater value was designated as the maximal voluntary contraction (MVC) torque. Participants then performed submaximal isometric contractions with the dorsiflexor and plantar flexor muscles to match target forces of 10% and 20% MVC torque with the self-reported less affected leg. The task was to match the target force displayed on the monitor and then maintain a steady contraction. The protocol comprised two 30-s trials at each target force with each muscle group. Force steadiness was measured as the coefficient of variation for force.

The NMES treatments were applied with an FDA-approved clinical device (Vectra Genisys Therapy System, DJO Global) that delivered symmetric, biphasic pulses of current through pairs of electrodes (2 x 3.5 in or 2 x 5 in each) placed on the skin overlying the muscles of each leg. NMES was applied to the dorsiflexor and plantar flexor muscles (10 min each muscle, 4-s on and 12-s off) of each leg. NMES was applied to one leg at a time in a counterbalanced order across sessions. Stimulus frequency was set at 100 Hz with a pulse width of 1 ms for wide-pulse stimulation and at 50 Hz with a pulse of 0.26 ms for narrow-pulse stimulation. To reduce the discomfort associated with NMES, the participant was encouraged to contract the involved muscles while the stimulation was being applied.

The stimulation was applied while the participant was seated during the first and last two weeks (12 sessions) of the intervention and while standing in the middle two weeks (6 sessions). In the seated position, the legs were lifted parallel to the floor and the subject pushed against a restraint during application of NMES. In the standing position, subjects stood in a lunge position when NMES was applied to the plantar flexors and with the heels placed on a platform when the NMES was applied to the dorsiflexors. Current was progressively increased across sessions to the maximal tolerable level for each participant and then tapered during the last 3 sessions. After ~19 evoked contractions, the participant performed three passive stretching exercises with the involved leg muscles. The treatment sessions were performed or supervised by a physical therapist with clinical experience in providing such treatments. Each treatment session lasted ~50 min.

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TRANSPARENT REPORTING of TRIALS

CONSORT 2010 Flow Diagram