

Feasibility of randomised clinical trial of early initiation and prolonged, home-based FES training to enhance upper limb functional recovery following stroke

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Abstract

Purpose: Test the feasibility and safety of early initiation and prolonged FES training to enhance upper limb functional recovery following ischemic stroke in a randomised clinical trial.

Method: The experimental group received 12-weeks of FES program plus standardized PT/OT rehabilitation while a severity matched (Fugl-Meyer score) group received standardized PT/OT rehabilitation alone over the 12-week period. Training began within 7-14 days of admission to acute rehabilitation and continued after discharge, at the patients' residence. Patients practiced 60 min every day. The experimental group combined PT/OT exercises with up to 4 hrs of daily FES to the forearm-wrist-hand flexors/extensors using the Handmaster™ FES system. The stimulation was combined with task-specific training tailored and modified to each patient's ability. Outcome measures of hand function (Box & Blocks [B&B]; Jebsen Taylor [J-T], and motor control (F-M) were recorded at baseline, 4, 8 and 12 weeks.

Results: To date, 9 patients completed the trial. All tolerated and complied with the daily training. At study end, the B&B mean score of the stimulated group was 34.7 % greater than the control group. Similarly the J-T task time was 34.8% faster and the F-M score 32.1% higher in the stimulated group. Six/nine patients improved hand function and 8/9 motor control.

Conclusion: RCT with early and prolonged FES is feasible and may provide considerably better functional recovery of the upper limb.

physiological reorganization of damaged central nervous system (CNS), the recognition that movement-dependent training is critical for successful recovery of neuromuscular control, and the growing appreciation of the peripheral and central electro-physiologic effects that FES can provide, all support the notion that FES could become a very important, first-line care intervention option in neuro-rehabilitation. No other intervention can provide an effective and repetitive sensory-motor system each day over prolonged time period. But one major deterrent to wide spread acceptance of FES by the clinical community is the inconsistent and poorly justified training dose. A sound rationale for FES dosage and time of initiation of upper limb retraining is long overdue and should be established.[1]

Current evidence clearly favour initiation of stimulation as early as medically and physically possible.[2-5] In contrast, FES training dose vs. patient response i.e. the association between stimulation duration and patients progress remains unknown. Most researches have reported training sessions that lasted only 20-60 min, 3-5 times per week and were terminated after 2-6 weeks regardless of individual patient improvement status and without any medical or otherwise credible rationale for terminating the intervention.[2-9] Our group is exploring the FES training dose question in a randomised clinical trial (RCT) that documents the relationships between clearly described and quantified training dose and recovery of upper limb function as well as volitional motor control up to 3 months. Herein, we report the feasibility of conducting a randomised clinical trial that starts at the rehabilitation centre and continues at the patient's residence.

1 Introduction

Utilization of FES as part of a conventional rehabilitation programs is uncommon in today's clinical practice. Understanding the patho-

2 Methods

Patients within 7-14 days of admission to rehabilitation hospital, first time ischemic stroke, upper limb paralysis (F-M score

between 2 and 40), and Folstein's mini-mental score >20, are randomly assigned to either standardized, task specific PT/OT (control group, mean age 67 yrs) or standardized, task specific PT/OT combined with FES that stimulate the wrist/fingers flexors and extensors (experimental group, mean age 69 yrs). The random group assignment is preceded by matching pairs of Fugl-Meyer (F-M) score within 10 points. Patients in both control and experimental groups receive an individually structured physical rehabilitation intervention while in the rehabilitation unit. The program is comprised of physical (PT) and occupational (OT) therapy (30 min session) aimed at promoting motor retraining of the paralysed muscles of the upper limb. The PT/OT training is individually tailored to each patient and constructed through selection of appropriate exercises. An "Exercise Bank" containing both simple and more complex list of task-specific, and upper limb functional exercises has been developed. The number and complexity of the exercises is adjusted for each patient so that he/she is able to perform them. The list is further modified for each patient as she/he improves upper limb performance. The determination of which exercises, how many, and the time each exercise is practiced is the responsibility of the research therapist. Each patient's exercise profile is documented using the exercise group number and letter. This method permits numerical summation of training progress.

Treatments are given twice a day, 5 days each week during hospitalisation. Upon relocation to the new residency the research therapist continues the standardized treatment once per week and the patient practice the rest of the daily program on her/his own.

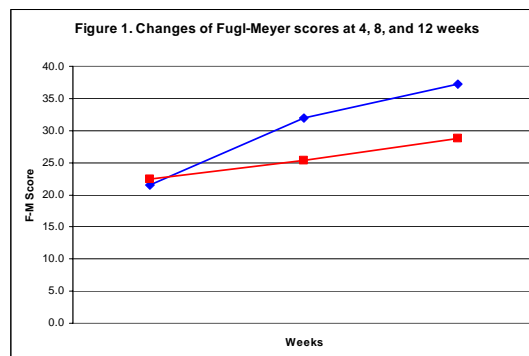
Electrical stimulation is provided by the Handmaster™ system (NESS, Ltd.), a microprocessor based FES system. In essence, the system is comprised of 3 sizes of forearm/hand moulded-orthosis and contains an array of five surface electrodes ranging in size from 2x2 to 6x4 cm. The electrodes are positioned over the extensor digitorum, extensor pollicis brevis, flexor digitorum superficialis, flexor pollicis longus and thenar muscles. Electrodes positions within the orthosis are custom-determined for each patient to optimise the contraction of the wrist and fingers flexors and extensors. Once the optimal position is determined, the 5 electrodes are secured within the orthosis. This individualized

electrodes position makes it very easy for the patient to get a consistent level of stimulation every day. The electrodes are connected to a stimulator that delivers alternating current (AC) at a carrier frequency of 11 KHz, time-modulated to bursts at 36 Hz. The stimulator is set in an interrupted pulses mode of with the contraction and relaxation intervals both set at 7 sec ON and 7 sec OFF. The microprocessor program enables stimulation of reciprocal finger flexion/extension as well as patterns of hand grasp and release.

Outcome measures include two functional tests the Box & Block (B&B), and light object lift sub-set of the Jebsen-Taylor (J-T) upper limb test and one volitional motor control (F-M score for the upper limb). The three outcome measures have shown reliable ICC of 0.9 or better. The upper limb F-M is digitally videotaped to allow unbiased scoring, while both functional tests are timed with a stopwatch. The three outcome measures are recorded at baseline, and after 4, 8, and 12 weeks of training.

3 Results

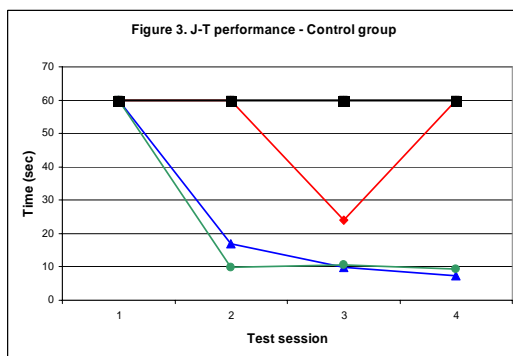
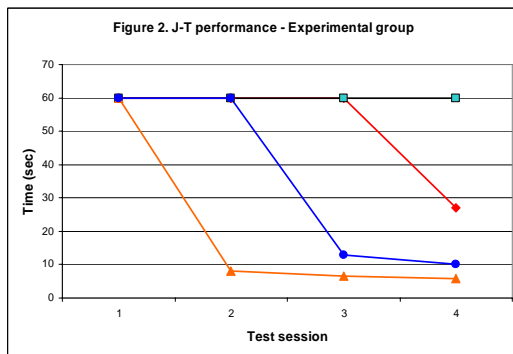
To date, 9 patients completed the 12 weeks trial. All tolerated the program well and there were no report of study-related adverse events such as recurrent stroke, TIA, cardiac episodes, shoulder subluxation, RSD or skin irritation. Patients' compliance with the daily FES training was about 80%. Baseline F-M score of the experimental group was 9.0 ± 5.7 and the control 10.0 ± 7.6 . Improvement of F-M score was nearly identical at week four, 21.5 ± 12.5 experimental and 21.8 ± 16 control groups. Differences between groups became evident at 8 and 12 weeks as illustrated in figure 1.



The box and block (B&B) test represents hand prehensile functional task of small object manipulation that only 1 patient in each group was able to perform at baseline. At 4 weeks, 2

experimental and 3 control patients were transferring respectively a mean of 10.5 (range 0-35) and 9.2 (range 0-24) blocks in 60 sec. At study end (week 12), 3 of 4 patients in experimental group averaged 20.7 (range 0-48) blocks compared to 3 of 5 patients in the control group that averaged 15.4 (range 0-43) blocks.

Individual patient's performance of the J-T test is summarized in figures 2 and 3.



As seen one patient in each group was unable to perform the task (60 sec is the ceiling time).

Improvement of the three patients in the experimental group, varied in onset of recovery, as well as performance time. Two patients in the control group recovered the ability to perform the J-T test within 4 weeks of study onset, one improved further at 8 and 12 weeks while the other plateau. One in the control group patient was able to perform the J-T test at 8 weeks but lost it due to loss of joint motion and increase spasticity at the end of data collection.

4 Discussion and Conclusions

Given the multitude of physical, behavioural, emotional, and practical rehabilitative deficits following stroke an early commenced and prolonged randomised clinical trial of FES training and the establishment training dose in

stroke rehabilitation is feasible. In fact our preliminary data suggest that effect size of FES may require small sample to meet adequate statistical power.

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