

# Home-based electromyography-triggered stimulation in chronic stroke

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**Objectives:** (1) To determine the feasibility of a home-based electromyography-triggered neuromuscular stimulation (ETMS) programme; and (2) to determine ETMS efficacy in increasing affected wrist extension and reducing affected arm impairment.

**Design:** Randomized, controlled, pre–post, cross-over design.

**Setting:** Outpatient rehabilitation hospital.

**Patients:** Twelve chronic stroke patients with palpable muscle contraction in their affected wrist extensors but no movement (7 males; mean age = 59.75 years, age range 44–75 years; mean time since stroke = 52.75 months, range 13–131 months).

**Intervention:** Subjects were randomly assigned to receive either: (a) ETMS use twice every weekday in 35-min increments during an eight-week period followed by an eight-week home exercise programme (ETMS/home exercise programme) ( $n = 8$ ); or (b) an eight-week home exercise programme followed by use of ETMS twice every weekday in 35-min increments during an eight-week period (home exercise programme) ( $n = 4$ ).

**Main outcome measures:** The Fugl-Meyer, Action Research Arm Test and goniometry.

**Results:** After home exercise programme participation, subjects showed nominal or no changes on any of the outcome measures. After ETMS, patients showed modest impairment reductions, as shown by the Fugl-Meyer, and no Action Research Arm Test changes. However, both groups showed a 21° increase in active affected wrist extension after ETMS use.

**Conclusion:** ETMS use is feasible in the home environment. Neither participation in a traditional home exercise programme nor ETMS use conveyed changes on the Fugl-Meyer or Action Research Arm Test. However, ETMS use increased active affected limb extension. This new movement may provide a potential pathway for subjects to participate in other interventions, such as modified constraint induced therapy.

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## Introduction

Individuals with stroke often exhibit compromised movement in the distal regions of their affected arms even years after their strokes,<sup>1</sup> which undermines performance of most activities of daily living (ADLs). Although several stroke motor therapy regimens have shown promise in chronic (> 1 year post stroke) patients,<sup>2-4</sup> most necessitate some initial active affected limb movement out of synergy. As a result, patients exhibiting negligible distal movement in their affected arms are usually discharged with significant residual motor deficits and a negative prognosis.

It is now believed that repeated affected limb use causes use-dependent neural changes in which adjacent cortical areas assume functions of damaged areas.<sup>5-7</sup> Limb use can be difficult and frustrating, though, for chronic stroke patients who have not progressed past the initial Brunnstrum stages.<sup>8</sup> Cyclic neuromuscular electrical stimulation involves stimulation applied to the affected muscle(s) to elicit muscle contraction(s). Several studies have shown increased affected arm function following cyclic surface neuromuscular electrical stimulation use in acute<sup>9,10</sup> and chronic stroke.<sup>11</sup> However, cyclic surface neuromuscular electrical stimulation may be suboptimal because patients are not encouraged to volitionally activate their muscles during neuromuscular electrical stimulation (i.e., their participation is passive).

As an alternative, surface electromyography-triggered neuromuscular stimulation (ETMS) incorporates concepts of repeated limb use, biofeedback, and electrical stimulation. When using ETMS, the patient attempts to activate the affected musculature (for the purposes of this paper, the affected extensors). If the intended muscles are activated such that a preset threshold is reached (as detected by electromyography in the device), the musculature is electrically stimulated by the device and full extension is realized. If the threshold is not reached, the threshold is automatically lowered, and the patient tries again. Thus, the patient is induced to attempt to activate the affected musculature, and, when successful, is provided with biofeedback that reteaches active muscle contraction via the reward of electrical stimulation.

ETMS appears to increase affected wrist movement in both subacute and chronic stroke patients

who, before intervention, exhibited trace active extension.<sup>12-15</sup> These changes appear to increase functional activity performance. For example, Kraft and colleagues<sup>14</sup> showed a 42% improvement on the Fugl-Meyer among patients who received ETMS, and Francisco and colleagues<sup>16</sup> showed a 17-point improvement on the Fugl-Meyer and a 3-point improvement on the Functional Independence Measure. Carrough and colleagues<sup>17</sup> showed that patients can self-administer ETMS in the clinic with minimal training and realize motor improvements.

## The current study

As noted above, recently developed motor interventions,<sup>2-4</sup> including ETMS,<sup>15-20</sup> show promise in stroke patients who initially exhibit affected arm active movement. It would be valuable to discern whether ETMS can be efficacious in more impaired patients. However, to our knowledge, no intervention has shown promise in stroke patients with flaccid affected arms. Furthermore, although stroke patients can don an ETMS machine in the clinic,<sup>17</sup> no studies have examined the feasibility and efficacy of ETMS when used at home in the most impaired patients. This information is fundamental to managed care reimbursement of home-based ETMS for community-dwelling stroke patients.

Using a randomized, cross-over design, purposes of this study were to: (1) determine the feasibility of a home-based ETMS programme when implemented with a frequency and duration similar to aforementioned ETMS clinical studies; and (2) determine ETMS efficacy in increasing affected wrist and finger extension and reducing affected arm impairment.

## Method

### Inclusion/exclusion criteria

Subjects for this study were recruited using advertisements placed in therapy clinics, and given to therapists and psychiatrists, in the Midwestern United States. A research team member screened volunteers using the following inclusion criteria: (1) stroke experienced between one year and 18 years prior to study enrollment; (2) no cognitive deficits, as evidenced by a score > 70 points on the

Modified Mini-Mental Status Examination<sup>18</sup>; (3) age > 18 < 85; (4) a detectable surface electromyography signal using the ETMS of > 0.2  $\mu\text{V}$  from the extensor carpi radialis of the more affected limb; (5) inability to actively extend the affected wrist (i.e., operationalized as trace movement, or palpable muscle contraction in the extensors but not movement); (6) passive range of motion to extension in the affected wrist to 45° from neutral, as well as passive movement without difficulty in the distal intercarpal joints of the affected fingers, both as measured by goniometry; and (7) completely discharged from all forms of physical rehabilitation. We also applied the following exclusion criteria: (1) excessive pain in the affected upper limb or wrist as measured by a score of  $\geq 5$  on a visual analogue scale; (2) neurologic comorbidity that impairs strength in the affected upper limb; (3) being administered medication that impairs neuromuscular performance (e.g., botulinum toxin A); (4) pregnant; (5) pacemaker or other implanted stimulator; (6) nonstroke-related wrist or finger pathologies (e.g., sprained wrist); and (7) participating in any other experimental studies.

### Apparatus

The Neuromove 900 (NM 900) (Stroke Recovery Systems Inc., Littleton, CO, USA) is an electromyography monitored neuromuscular electrical stimulation device approved by the federal Food and Drug Administration for use by stroke survivors. The NM 900 uses three reusable, self-adhering, 2.0" (diameter), round surface electrodes (one ground over a bony protrusion; two active electrodes over the motor point of the targeted muscle). One active electrode is placed on the posterior forearm (on the extensor group) 1 in (2 cm) from the elbow crease while the other is placed approximately 1 in (2 cm) below the first active electrode. The ground electrode is placed anywhere on the forearm as long as it is at least 3 in (8 cm) away from either active electrode. The goal of the electrodes is to detect electromyography in the affected muscles, and to provide stimulation to them. A computer inside the device evaluates the amount of activity present in the muscle, and determines whether the patient's muscle activity meets or exceeds a preset threshold. If the subject attains the threshold, the NM 900 activates the muscle with its own biphasic waveform with pulse

width ranging between 100 and 400  $\mu\text{s}$ . The on signal duration can be adjusted to be between 0.5 s and 10 s, but research suggests 10 s is the optimal<sup>19</sup> duration and was, thus, used in this study. The NM 900's safety and efficacy have been repeatedly demonstrated with no side-effects.

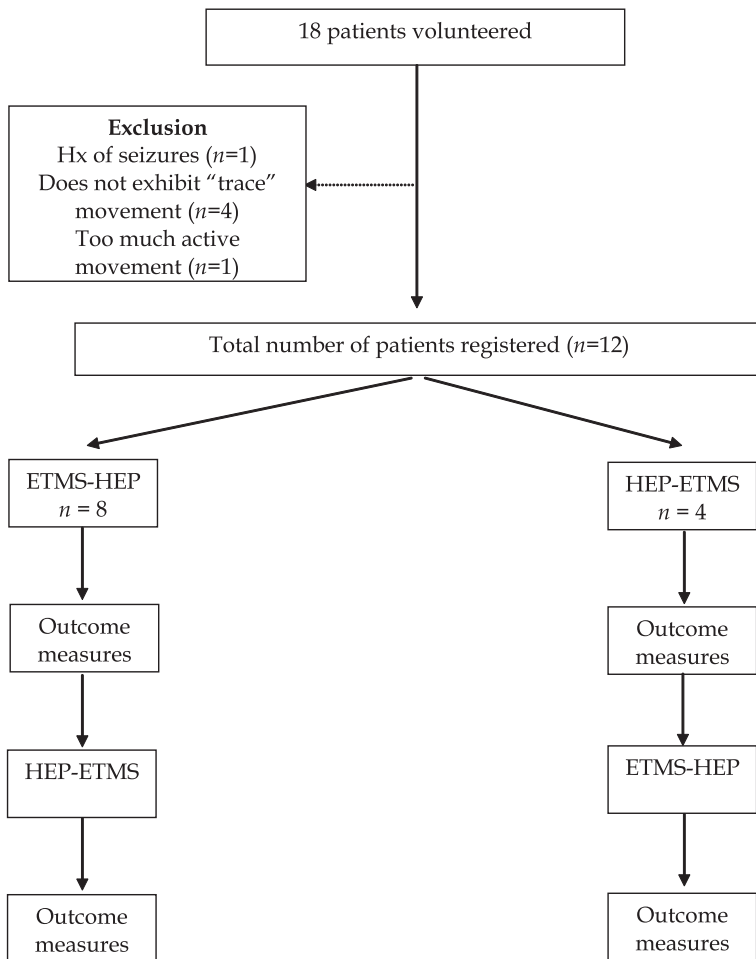
### Instruments

A pluri-dig, hyperextension finger goniometer (Sammons-Preston, Cederburg, WI, USA) was used to measure active wrist extension before and after intervention. The small, plastic device can be held and operated with one hand and, using a protractor measuring from 0° to 110° in 2° increments, is sensitive to small changes in active extension. As noted previously, active wrist movement is fundamental to gaining access to several promising interventions. Consequently, active wrist extension was chosen as the only outcome to be measured by goniometry.

In addition to goniometry, we applied the following measures due to their sensitivity to motor changes in chronic stroke<sup>20</sup>: (1) the Fugl-Meyer Scale<sup>21</sup> assesses several dimensions of impairment. The upper extremity motor component, which consists of 66 points, was used in this study, and has been shown to have impressive test-retest reliability (total = 0.98–0.99; subtests = 0.87–1.00), inter-rater reliability and construct validity.<sup>22,23</sup> (2) The Action Research Arm Test,<sup>24</sup> a 19-item test divided into four categories (grasp, grip, pinch, and gross movement), with each item graded on a four-point ordinal scale (0 = can perform no part of the test; 1 = performs test partially; 2 = completes test but takes abnormally long time or has great difficulty; 3 = performs test normally) for a total score of 57. The ARA also has high intra-rater ( $r = 0.99$ ) and retest ( $r = 0.98$ ) reliability and validity,<sup>24,25</sup> and has been used extensively in stroke intervention studies.

### Design, pretesting and intervention

A randomized, single-blinded, pre/post test cross-over case series design was applied. After screening and signing consent forms approved by the local institutional review board, the Fugl-Meyer and Action Research Arm Test were administered on two occasions one week apart by a research team member. Following the second pretesting session, patients were randomly assigned



**Figure 1** Flow diagram for this study.

to one of two groups using a random numbers table: (1) ETMS/home exercise programme; (2) home exercise programme/ETMS. Our study design is depicted in Figure 1.

### ETMS/home exercise programme

One week after the second pretesting session, patients assigned to the ETMS/home exercise programme group received a 30-min, individualized education session in which they were taught how to use the device by a research team member. At the conclusion of the session, patients were given written directions, as well as a picture depicting proper electrode placement. Patients were also given sample electrodes to take home

and practice electrode placement. One week later, patients returned to the laboratory and were tested on placement by a physician team member. Patients were then given an ETMS device and a home use diary in which they were to record their use of the device.

At home, ETMS/home exercise programme patients used the ETMS device twice every weekday in 35-min increments during a eight-week period. The duration, frequency, and number of weeks of sessions was based on manufacturer recommendations. Furthermore, previous ETMS studies had used comparable parameters, such as the 10-s cycles recommended by Cauraugh and colleagues.<sup>19</sup> During times of device use, surface

electrodes were placed on the wrist extensors, and a ground electrode was placed on the olecranon process. While practising ETMS at home, subjects practised extension exercises without participation in any actual activity. After 8 weeks, ETMS/home exercise programme patients returned to the laboratory and a physician team member checked skin integrity. During this visit, patients also returned the device, their ETMS home use diaries, and were administered goniometry, the Fugl-Meyer, and the Action Research Arm Test. Lastly, subjects were given a sheet with a list of home exercises for the more affected limb, and a home use diary to record their compliance with the home exercise programme. The exercise sheet, which also provides pictures and written descriptions of each exercise, was commonly administered at discharge from outpatient physical therapy and was thus identical to those exercises that discharged stroke patients would normally be practising at home. As such, this was an adequate reference condition. After being shown how to perform each exercise by a team member, subjects were instructed to perform the home exercises twice every weekday for 35 min. The entire visit took approximately 1 h. Specific affected limb exercises in the home exercise programme included: supination/pronation exercises; flexion and extension of the individual fingers; wrist extension and flexion exercises; elbow flexion and extension exercises; and shoulder adduction and abduction exercises.

### Home exercise programme/ETMS

Patients randomly assigned to the home exercise programme/ETMS group participated in the two, above-described programmes (ETMS and home exercise programme), but in the opposite order. That is, they received a 1-h testing and education session concerning the home exercise programme, and performed the programme for eight weeks (35 min; twice/weekday). After eight weeks of participation in the home exercise programme, subjects returned to the laboratory, where the outcome measures were again administered and the patients were taught how to use the ETMS device. After one week of practising electrode placement, they returned to the laboratory, were given an ETMS device, and used the device at home for eight weeks according to the above-described parameters.

### Posttesting

After 17 weeks, each patient returned to the laboratory and the Fugl-Meyer, Action Research Arm Test and goniometry were again administered by the same team member who initially administered the instruments. He was blinded to group assignment throughout the study.

### Results

Using the above inclusion/exclusion criteria, 12 individuals were included (7 males; mean age = 59.75 years, age range 44–75 years; mean time since stroke = 52.75 months, range 13–131 months; seven strokes exhibiting upper limb hemiparesis on dominant side) (Table 1).

Before intervention, subjects uniformly exhibited inability to functionally use their more affected wrists and fingers. Indeed, an ARA mean score of 1.428 was observed in the ETMS/home exercise programme group (Table 2), which reflected ability to partially perform 1–2 ARA items. Similarly, a mean Action Research Arm Test score of 0 was observed in home exercise programme/ETMS subjects before intervention (Table 2). Mean Fugl-Meyer group scores were also nearly identical between groups before intervention; the mean Fugl-Meyer score for the ETMS/home exercise programme group was 12.0; the mean Fugl-Meyer score for the home exercise programme/ETMS group was 15.83 (Table 2). Subjects in both groups exhibited selected proximal function as measured by the Fugl-Meyer (e.g., shoulder abduction; elbow flexion), but limited distal function.

Preintervention more affected wrist extension levels were also similar for both groups; the mean affected wrist extension level for the ETMS/home exercise programme group was 15.125° before intervention; the mean affected wrist extension level for the home exercise programme/ETMS group was 12.75° before intervention (Table 3). All subjects' affected upper limb motor function had not changed since outpatient occupational therapy discharge, per their medical records, and as confirmed by their physicians.

After participating in ETMS, subjects in the ETMS/home exercise programme group exhibited

**Table 1** Subject characteristics

Gender	Age	Months since CVA	Side affected	Group
M	54	52	L	ETMS/HEP
M	60	68	R	ETMS/HEP
F	65	131	L	ETMS/HEP
F	65	36	L	ETMS/HEP
F	75	60	R	ETMS/HEP
F	58	29	R	ETMS/HEP
M	70	127	L	ETMS/HEP
M	55	42	R	ETMS/HEP
M	59	46	R	HEP/ETMS
F	44	13	R	HEP/ETMS
M	62	16	L	HEP/ETMS
M	50	13	L	HEP/ETMS

HEP, home exercise programme; ETMS, electromyography-triggered neuromuscular stimulation.

a 6.875 point increase on the Fugl-Meyer, an increase of  $<0.1$  points on the Action Research Arm Test, and an increase of  $21.25^\circ$  in active wrist extension, all compared to preintervention levels. After subsequently participating in the home exercise programme, subjects in the ETMS/home exercise programme group lost many of the gains that they had exhibited via ETMS. Specifically, they exhibited a  $-8.8$  point decrease on the Fugl-Meyer, a  $-1.5$  point decrease on the Action Research Arm Test, and  $-4.09^\circ$  decrease in affected wrist extension.

Subjects in the home exercise programme/ETMS group exhibited similar reactions to the two interventions as those in the ETMS/home exercise programme group. Specifically, after eight weeks of home exercise programme participation, Fugl-Meyer scores increased by 0.55 points, Action Research Arm Test scores increased by 0 points (Table 2), and active affected wrist extension decreased by  $1.75^\circ$  (Table 3). Conversely, after ETMS participation, Fugl-Meyer scores and Action Research Arm Test scores changed nominally, but active wrist extension increased by  $21.25^\circ$ .

## Discussion

Stroke patients are often unable to perform valued activities with their affected arms due to diminished active, distal movement. Few motor therapies are available for patients exhibiting minimal distal movement in their affected arms, and no home-based therapies have shown efficacy for this group. This study examined the efficacy of home-based electromyography triggered neuromuscular stimulation (ETMS) on the motor function of chronic stroke patients' affected arms.

An advantageous feature of the NM 900 is its ability to quantify the amount of device use in which subjects engaged. In this study, subjects were highly compliant with ETMS use, as shown by the device. Moreover, on days in which ETMS was employed, patients used the device for the entire duration. Patients and their caregivers also each reported high compliance with the ETMS protocol in their home use diaries; only four instances of nonuse reported during the ETMS portion of the protocol. Subjects and their caregivers, who had been educated on device use as part of study

**Table 2** Patient mean scores on the Fugl-Meyer and Action Research Arm Test before and after intervention

Group	FM			ARA		
	Pre	After 8 weeks	After 16 weeks	Pre	After 8 weeks	After 16 weeks
ETMS/HEP ( $n=8$ )	12.0	18.875	11.0	1.428	1.571	0
HEP/ETMS ( $n=4$ )	15.83	16.38	16.54	0	0	0

HEP, home exercise programme; ETMS, electromyography-triggered neuromuscular stimulation.

**Table 3** Pre–post changes in affected wrist extension using goniometry

Group	Preintervention extension	After 8 weeks	Change from pre	After 16 weeks	Change from week 8
ETMS/HEP	15.125°	36.375°	+21.25°	32.285°	– 4.09°
HEP/ETMS	12.75°	11.00°	– 1.75°	32.25°	+21.25°

HEP, home exercise programme; ETMS, electromyography-triggered neuromuscular stimulation.

participation, also reported no problems using the NM 900 at home. Together, these data suggest that home ETMS use is feasible with high compliance.

Home use logs also suggested that subjects were compliant, although to a lesser degree, with the home exercise programme. Specifically, 27 instances of not performing the programme as scheduled were reported in the home use diaries. Lack of compliance with the home programme may be a partial explanation for the subsequent losses of motor function that subjects exhibited. However, we also suspect that the ETMS intervention is substantially more motivating and robust, particularly given previous ETMS research findings.

Before intervention, subjects displayed stable motor deficits and consistent impairment levels, fine motor function levels (Table 2), and more affected wrist extension levels (Table 3), regardless of group assignment. According to their physicians and/or their medical records, their motor levels had not changed since discharge from outpatient motor therapy. Subjects uniformly reported inability to perform functional activities.

After ETMS participation, ETMS/home exercise programme subjects exhibited a 7.875-point increase on the Fugl-Meyer (Table 2), primarily due to increased voluntary movement in the distal areas (e.g., wrist extension). This change was supported by increased active extension of the affected wrist increased by  $>21^\circ$  (Table 3). Interestingly, some subjects in this group also showed increased shoulder movement on the Fugl-Meyer (e.g., abduction, retraction). We believe that this improvement was because, when attempting to extend the fingers, many subjects also moved their shoulders and arms (although instructed not to by research team members). ETMS/home exercise programme subjects exhibited no changes on the Action Research Arm Test after ETMS participation. After home exercise programme participa-

tion, subjects in this group exhibited no changes on the Fugl-Meyer, Action Research Arm Test, or in goniometry. Thus, only ETMS participation caused motor changes, and these changes, while not functional, were quite large in terms of ability to actively extend the affected wrist.

Subjects in the second study group received a home exercise programme first, followed by ETMS. Like their counterparts in the other study group, members of the home exercise programme/ETMS group showed no changes, or nominal changes, on the Fugl-Meyer, Action Research Arm Test or goniometry after home exercise. However, after ETMS participation, subjects in the home exercise programme/ETMS group exhibited a mean increased active extension in their affected wrists by  $>21^\circ$  (Table 3). This finding was consistent with the direction and magnitude of active extension changes observed in the other group following ETMS use. Interestingly, participants in the second group did not exhibit the Fugl-Meyer changes exhibited by members of the first group. We are uncertain why this difference occurred.

Together, our data suggest that ETMS conveys limited impairment reduction and functional improvements for flaccid chronic stroke patients, regardless of its timing. Indeed, stroke patients, when asked after ETMS application, were not able to perform any new valed activities as a result of participation. However, ETMS appears to substantially increase active affected wrist extension in flaccid stroke patients, regardless of the timing of its administration. This is an important discovery, given that, to our knowledge, no intervention has shown promise in increasing active affected wrist extension in this group. In fact, ETMS may be a pathway whereby stroke patients exhibiting minimal active extension can regain needed extension to participate in other interventions. Consistent with this suggestion, active extension increases

from ETMS enabled several subjects to participate in modified constraint-induced therapy and realize additional motor gains in their more affected wrists and fingers. We recognize that a study limitation is lack of formal measurement of functional improvement and we recommend that future authors examine this possibility. We also recognize that, as often happens, the randomization pattern happened to lead to unequal numbers in the groups (see Figure 1). This shortcoming argues for additional ETMS studies with more robust sample sizes and equal groups before substantive conclusions can be drawn.

Data by Kimberley and colleagues<sup>26</sup> suggest a relationship between ETMS provision, improvements on laboratory measures, and cortical changes. However, recent reviews<sup>27,28</sup> note several shortcomings of ETMS studies, including small sample sizes, limited use of functional outcome measures, and unequal ETMS treatment durations. Similarly, although only a pilot study, findings of this study need to be replicated with a larger sample size and equal numbers in each study condition, each of which would overcome limitations of the current study. The optimal ETMS duration for flaccid stroke patients also needs to be identified in future work, particularly in relation to less impaired patients. Indeed, it seems reasonable that flaccid stroke patients may require a longer ETMS programme with more sessions of longer durations than less impaired patients. In the current study, we believe that repeated ETMS use caused cortical changes that resulted in changes in extension as described earlier. We are currently

investigating this hypothesis and resolving the above limitations by examining the functional and neural effects of several ETMS durations using functional magnetic resonance imaging at 4 Tesla.

## Conclusion

ETMS does not appear to convey a functional benefit to flaccid chronic stroke patients. However, ETMS consistently and markedly increases active wrist extension, providing a potential pathway by which patients could participate in other promising interventions. More research is needed concerning the optimal duration, timing, and mechanisms of ETMS in flaccid chronic stroke.

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### Clinical messages

- Electromyography triggered neuromuscular stimulation (ETMS) does not convey functional benefits to stroke patients with limited active wrist extension.
- ETMS does, however, appear to increase active wrist extension, regardless of time of presentation.
- ETMS may be a pathway by which patients exhibiting no movement may become eligible for other protocols, such as modified constraint-induced therapy.



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