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Home-based neuromuscular electrical stimulation (NMES) program for chronic post-stroke lower limb spasticity: A single-arm pilot study

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Abstract

Background & Objectives: Post-stroke spasticity often leads to gait abnormalities, posing challenges for patients. Non-invasive neuromuscular electrical stimulation (NMES) offers a promising avenue for treatment. Despite the availability of portable NMES devices, there is a gap in understanding patient perceptions and outcomes of home-based NMES programs targeting lower limb spasticity post-stroke. This single-arm pilot study aimed to assess the impact of a home-based NMES program on spastic ankle plantar flexors and the feasibility of the program. Primary objectives focused on spasticity levels, ankle range of motion (ROM), dorsiflexor strength, walking speed, and lower-extremity function, while secondary objectives included retention rates, adherence rates, and patient feedback. *Methods:* Participants with plantar flexor spasticity rated Modified Ashworth Scale (MAS) 1+ to 3 received 20-minute NMES sessions daily, 5 days/week, for 4 weeks alongside conventional rehabilitation. Primary objectives were assessed using the MAS, Medical Research Council (MRC) scale, 10 meter walk test (10MWT), and Fugl-Meyer Assessment of Lower Extremities (FMA-LE), while secondary objectives were evaluated using structured questionnaires. *Results:* Ten participants were recruited, and nine completed the study with high adherence rates. All completers adhered to 20 sessions, except for one patient who completed 80% of the sessions. Positive feedback was received, and no adverse effects were reported. Significant improvements were noted in ankle ROM (5.56 degrees ± 3.38, p-value = 0.002) and spasticity (MAS reduction of 0.55 ± 0.93, p-value = 0.013). However, other functional outcomes did not show any significant improvement.
Conclusion: The home-based NMES program proved feasible and was well received by chronic stroke patients, demonstrating notable enhancements in ankle range of motion (ROM) and, to some extent, improvements in spasticity levels. Larger randomized controlled trials are warranted to further validate its potential benefits and effectiveness.

Keywords: Electrical stimulation therapy, lower extremity, neurological rehabilitation, spasticity, stroke

INTRODUCTION

Spasticity is a common complication post-stroke, with its prevalence ranging from 19% at 3 months post-stroke to 46% at 12 months post-stroke.[1-3] Spasticity is defined as a 'motor disorder characterized by a velocity-dependent increase in tonic stretch reflexes with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflex, as one component of the upper motor neuron syndrome'.[4] The repercussions of post-stroke spasticity are profound; along with weakness and lack of coordination, it has deleterious effects on gait, functional activities, and health-related quality of life among stroke survivors. This condition also imposes considerable strain on caregivers, translating

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into elevated care demands and socioeconomic burden.[5] A study in Sweden reported a fourfold increase in direct costs for post-stroke patients with spasticity compared to those without spasticity.[6]

There are several treatment options for managing spasticity, including physical therapy, the use of ankle-foot orthosis (AFO), oral medications such as baclofen and tizanidine, chemodenervation with botulinum toxins (BoNT), phenol, or alcohol, intrathecal baclofen therapy, and surgical interventions.[7,8] Oral medications can effectively reduce spasticity; however, their use is limited by numerous adverse side effects. In recent years, a range of non-pharmacological interventions or physical modalities have been used to manage spasticity. These include transcranial direct current stimulation (tDCS), repetitive transcranial magnetic stimulation (rTMS), and neuromuscular electrical stimulation (NMES).[7-10] NMES refers to a therapy that applies electrical currents to induce tetany and contraction of innervated muscles by depolarizing local motor nerves. In stroke rehabilitation clinical practice, NMES has been recommended for promoting limb strength and functional recovery in both acute and chronic stroke, as well as a treatment for hemiplegic shoulder subluxation, loss of hand and upper extremity function, and gait impairment resulting from foot drop and ankle plantar flexor spasticity.[11] It has been hypothesized that NMES reduces spasticity by stimulating the antagonist muscle, causing plastic effects within the spinal cord circuits, including disynaptic reciprocal Ia inhibition, presynaptic inhibition of Ia terminals, and post-activation depression.[12]

Currently, there is a range of devices that deliver NMES, including battery-operated, portable devices that are readily accessible to patients. Moreover, with the recent COVID-19 pandemic affecting neurological rehabilitation care in hospital and community settings, there is a need to establish a home-based program essential for the rehabilitation care continuum.[13,14] Therefore, this study aims to evaluate the impact and feasibility of a home-based program using NMES on plantar flexor spasticity following stroke. Notably, this study represents the first of its kind within our local population. Before proceeding to a larger randomized controlled trial to define its effectiveness in improving clinical outcomes, a pilot study is deemed necessary to assess its feasibility and apparent impact.

METHODS

Participants were recruited from referrals at the rehabilitation clinic and physiotherapy gymnasium of Universiti Malaya Medical Centre (UMMC), Kuala Lumpur, Malaysia, between December 2020 and November 2021. The research team screened referrals based on the inclusion criteria, which included patients with a history of haemorrhagic or ischemic stroke with ankle plantar flexor (gastrocnemius) spasticity rated from Modified Ashworth Scale (MAS) 1+ to MAS 3, stroke duration of more than 6 months, age over 18 years, ability to ambulate at least 10 meters independently or with the aid of a single-point stick or quadripod, compliance with outpatient therapy, minimal cognitive impairment (MMSE > 24), minimal sensory impairment, and stable neurological and medical condition.

The exclusion criteria are as follows: introduction or changes in anti-spastic medication dose within 3 months or during the study period; receiving interventions for spasticity (e.g., BoNT injection or serial casting) within 3 months or during the research period; new neurological condition/disease; presence of contraindications to NMES, including pregnancy, malignancy, presence of electronic implants such as cardiac pacemaker/cardioverter defibrillator; uncontrolled seizure/epilepsy; infected tissues/tuberculosis or osteomyelitis; impaired lower limb circulation/DVT/thrombophlebitis; recent fracture or osteoporosis; actively bleeding tissue or a person with an untreated haemorrhagic disorder; damaged or diseased skin on the affected lower limb.[15]

Study design and intervention

This was a prospective intervention study with a pre-test and post-test design, implementing a home-based NMES program targeting the lower limbs over a duration of 4 weeks. Prior to commencing the study, all participants underwent a training session on the application of the surface electrodes and the operation of a portable NMES device (Neuromuscular stimulator, Rehalito, MTR Plus Vertriebs GmbH, Berlin, Germany). This initial training ensured that participants could apply the electrodes and operate the devices without issues. The self-adhesive surface electrodes (size: 5.0 cm x 5.0 cm) were positioned over the common peroneal nerve outlet (below the fibular head) and the tibialis anterior muscle.[9,16] Participants were instructed to use the NMES device at home for 20 minutes per session daily, five days a week, totaling 4 weeks (20 sessions

in total). The NMES stimulation parameters were as follows: biphasic current, frequency 50 Hz, pulse width 400 μs, ON:OFF 10 sec:20 sec. The stimulation intensity was individually adjusted to the maximum tolerated amplitude to achieve ankle dorsiflexion. During stimulation, participants were instructed to sit with their soles in contact with the floor and attempt to dorsiflex voluntarily. The participants were also advised to continue their routine stretching exercises of the plantar flexors after the session. They were given an instructional pamphlet for the stretching exercises: hold each stretch for 10-30 seconds, with 10 to 20 repetitions daily after NMES. Participants' compliance with home sessions was recorded through daily log sheets and device memory records.

Measurements

The pre- and post-intervention assessments were conducted by a rehabilitation medical officer with the assistance of a neuro-physiotherapist, which were trained in MAS, ROM and all the outcome measures. This is to minimize error, as the inter-rater reliability for the MAS is poor compared to intra-rater reliability.[17]

Outcome measures were assessed at the initial study and after completion of the 4-week study. The clinical measurements include various parameters such as:

Modified Ashworth Scale (MAS) level: MAS is used as the clinical measurement for plantar flexor spasticity. It employs a 6-point numerical scale grading spasticity from 0 to 4 (MAS 0, 1, 1+, 2, 3, and MAS 4), where MAS 0 indicates no resistance and MAS 4 indicates complete limb rigidity in flexion or extension.[17] To facilitate analysis and comparison, a modified-MAS level ranging from 0 to 5 was utilized (with MAS 1+ transformed to m-MAS 2, MAS 2 to m-MAS 3, MAS 3 to m-MAS 4, and MAS 4 to m-MAS 5).[18-20] This scale was assessed with the patient lying supine and the knee extended.

Passive Range of Motion (ROM): Ankle dorsiflexion maximal passive range of motion (ROM) was measured with a goniometer in a supine position with extended knees, and assessed relative to the neutral position, i.e., at 0 degrees (plantigrade).

Medical Research Council (MRC) Grading: Ankle dorsiflexor muscle strength was assessed using the MRC Manual Muscle Testing, which employs a scale ranging from 0 to 5 to grade muscle strength: MRC grade 0 indicates no contraction, MRC grade 1 indicates flicker or trace of contraction, MRC grade 2 indicates active movement with gravity eliminated, MRC grade 3 indicates active movement against gravity, MRC grade 4 indicates active movement against resistance, and MRC grade 5 indicates normal strength.[21]

10 Metre Walk Test (10MWT): The 10MWT is a performance measure used to assess walking speed in meters per second (m/s) over a 10-meter distance. Participants were allowed 3 trials of the 10MWT, and the results were averaged for the outcome.

Fugl-Meyer Assessment of the Lower Extremity (FMA-LE): FMA-LE is a stroke-specific, performance-based impairment index.[22] It scores lower limb motor function based on items assessing lower limb reflexes and synergy movement, with a maximum score of 28.

Feasibility and acceptability

The feasibility and acceptability were further evaluated based on the retention rate (defined as the proportion of participants who completed the program) and each participant's adherence rate. We considered good adherence as completing at least 75% of the sessions (15 out of 20). Additionally, participants' perception of the home-based NMES program was assessed at the end of the 4-week period using a brief questionnaire (adapted from a previous study by Windholz *et al*., 2014)[23] employing a 5-point Likert scale to rate their responses from 1 = 'strongly disagree' to 5 = 'strongly agree'. Participants were also asked to report any side effects experienced during the program.[11]

Statistical analysis

Due to the small sample size, Microsoft Excel 365 Version 16.5 (22011101), 2021 was used to collate and analyze the data. Quantitative data were reported using descriptive statistics, including means (± standard deviations). Pre- and post-intervention measures were compared using paired sample t-test analysis, with a p-value <0.05 considered statistically significant.

Ethical approval

This study complies with the ethical standards of the Declaration of Helsinki, and the protocol has

been approved by the local ethics committee of our university (UMMC Medical Ethics, MREC ID: 2020427-8560). Participants signed a written informed consent before participating in the study. The study was also registered in the National Medical Research Register (NMRR ID Number: NMRR-21-1117-60230) under the Ministry of Health, Malaysia, and on the ClinicalTrials.gov web-based registry (ID: NCT04932668 and protocol ID: 2020427-8560).

RESULTS

From December 2020 to November 2021, 16 patients were referred to the investigators for the study. Out of these, 10 fulfilled the criteria and consented to participate. The demographic characteristics of the participants are shown in Table 1. Among them, 80% (n=8) were male and 20% were female, with a mean age of 56.7 (±8.69) years. The majority had ischemic stroke (70%) and left hemiparesis (80%). The average time since stroke was 42.1 (±30.09) months, ranging from 9 to 90 months. Seventy percent used a quadripod for ambulation outdoors, while 30% ambulate independently without any assistive walking aid. Six of the participants have diabetes; however, the time of diagnosis was not known. All participants completed the study, except for one who dropped out due to COVID-19 infection during the study, leading to hospitalization due to deconditioning and regression of function. Due to the small sample size, we conducted descriptive analysis of the study.

The treatment effect with NMES devices for all completers is shown in Table 2.

All completers demonstrated improvement in ankle ROM, with a mean improvement of 5.56 (±3.38) degrees and among the nine completers, five of them exhibited a reduction of 1 level in MAS post-intervention. The participants also showed some improvement in the functional outcome, specifically in the 10MWT; however, only 2 participants (F and I) showed substantial improvement (10MWT > 0.10 m/s) as reported in other studies[24,25]. No significant changes were found in ankle dorsiflexion strength and function based on MRC grading and FMA-LE score of the lower limb.

Statistical analysis and mean values of the clinical outcome measures are presented in Table 3.

Feasibility and acceptability

Nine out of 10 participants completed the study, resulting in a retention rate of 90%. The participant who dropped out (n=1) completed 3 weeks of home-based NMES before contracting COVID-19 and was hospitalized. Among those who completed the study, 88% (n=8) adhered to all 20 sessions during the study period, with one participant achieving 80% adherence. Overall, all nine participants achieved more than 75% adherence, which is considered good adherence.

The feedback responses to the questionnaires

Table 1: Demographic characteristics of participants

Characteristic	Participants recruited (n=10)	Patient completed (n=9)
Sex	n (%)	n (%)
Male	8 (80%)	7 (77.8%)
Female	2 (20%)	2 (22.2%)
Age (mean in years ± SD)	56.7 ± 8.69	53.71 ± 8.44
Hemiparetic side		
Left	8 (80%)	7 (77.8%)
Right	2 (20%)	2 (22.2%)
Type of stroke		
Ischemic stroke	7 (70%)	6 (66.7%)
Hemorrhagic stroke	3 (30%)	3 (33.3%)
Duration since stroke (mean in months ± SD)	52.63 ± 30.09	37.86 ± 30.39
DM as comorbidity	6 (60%)	5 (55.5%)
Ambulation Independent	3 (30%)	3 (33.3%)
With quadripod	7 (70%)	6 (66.7%)

SD, standard deviation.

Table 2: Comparison of outcome measures pre- and post- intervention for each participant

Participants	Age	m-MAS level		Passive ROM		10MWT (m/s)		MRC grading	
		Pre	Post	Pre	Post	Pre	Post	Pre	Post
A	49	2	1	0	8	1.00	1.09	5	5
B	65	3	3	-12	0	0.38	0.44	4	5
C	65	2	2	-4	-2	0.14	0.16	1	1
D	51	2	1	0	4	0.65	0.61	1	1
E	42	3	3	-4	0	0.20	0.23	1	1
F	52	4	3	-10	0	0.90	1.21	1	2
G	52	2	1	0	6	0.88	0.94	5	5
H	62	2	2	0	0	0.25	0.25	0	0
I	69	2	1	10	14	0.25	0.39	0	0

were generally positive, as shown in Table 4. All participants agreed that using the NMES device for 20 minutes daily over 4 weeks was acceptable. Moreover, majority of the participants expressed interest in continuing the home-based NMES program beyond the study and would recommend it to other post-stroke patients. More than 50% felt that the home-based NMES program positively impacted their spasticity and ambulation. Overall, all participants found the home-based NMES program to be beneficial, and they reported that the NMES device was easy to use. The device demonstrated a good safety profile, as none of the participants reported serious or recurrent side effects, nor did they experience skin irritation or burns. The most commonly reported side effects were occasional mild pain and discomfort.

DISCUSSIONS

Electrical stimulation (ES) has been utilized in stroke rehabilitation in various forms: neuromuscular ES (NMES), transcutaneous ES (TENS), and functional ES (FES). Moe and Post introduced the term 'functional electrical stimulation' (FES) to describe the use of NMES to activate paralyzed muscles in a precise sequence, facilitating functionally useful movements such as lower limb standing and walking, as well as upper limb performance of activities of daily living.[26,27] NMES and FES have been previously studied as non-invasive modalities for post-stroke spasticity, showing promising positive effects when combined with other modalities.[9,28] However, there is a knowledge gap regarding

Table 3: Analysis of outcome measures pre- and post-intervention

Parameters	Completed participants (n=9)			
	Pre-treatment (mean ± SD)	Post-treatment (mean ± SD)	Difference (mean ± SD)	p-value
Spasticity (m-MAS level)	2.44 ± 0.73	1.8 ± 0.93	0.55 ± 0.53	0.013*
Passive dorsiflexion (ankle ROM)	-2.22 ± 6.43	3.33 ± 5.20	5.56 ± 3.38	0.002*
Ankle dorsiflexion strength (MRC grading)	2 ± 2.06	2.22 ± 2.16	0.22 ± 0.44	0.17
10MWT (m/sec)	0.52 ± 0.34	0.59 ± 0.39	0.08 ± 0.10	0.060
FMA-LE	18.0 ± 4.21	19.44 ± 3.54	1.44 ± 2.13	0.076

*p-value<0.05 is considered statistically significant

SD, standard deviation; MAS, Modified Ashworth Scale; ROM, range of motion; MRC, Medical Research Council; 10MWT, 10 meter walking test; m/sec, meter per second; FMA-LE, Fugl-Meyer Assessment-Lower Extremities.

Table 4: Participants' responses to questionnaires after completing the intervention

No.	Questions Text	Response range	Mean
1.	Using the NMES for 4 weeks is acceptable	4-5	4.44
2.	Using NMES for 20 minutes a day is acceptable	4-5	4.44
3.	Using NMES had a positive impact on my lower limb spasticity	2-5	3.66
4.	Using NMES had a positive impact on my ambulation	2-5	3.77
5.	I would continue/repeat the NMES program after the study	3-5	4.11
6.	I would recommend this program to my colleagues/other patients	3-5	4.33
7.	Overall, I think the homebased NMES program is a good intervention	4-5	4.33
8.	I would consider buying the device if the price is affordable	2-5	3.77
9.	The NMES device is simple to use	4-5	4.44
10.	Most of the time I can handle the device independently.	3-5	4.33
11.	It is easy to put on the surface electrode to the lower limb.	4-5	4.33
12.	I can use the surface electrode independently	3-5	4.22

Note: Participants used a 5-point Likert scale to rate their answers: 1 = 'strongly disagree', 2 = 'disagree', 3 = 'neutral', 4 = 'agree', 5 = 'strongly agree'.

home-based NMES programs for lower limb spasticity in our local population. Therefore, this pilot study in Malaysia aims to investigate a home-based NMES program in ambulatory post-stroke individuals with lower limb spasticity, including assessing their acceptability and perception of the program.

Our results showed significant improvement, particularly for ROM as shown is almost all completers and to some extent in ankle plantar flexor spasticity as observed in half of the participants. This finding is consistent with previous randomized controlled trials (RCTs) that utilized electrical stimulation of the same antagonistic muscle in combination with either an inpatient or daily outpatient rehabilitation program.[16,18,29,30] This study implemented a home-based program that empowered participants through structured NMES application along with routine stretching exercises for the plantar flexors. There is no clear consensus on the optimal stimulation parameters; however, it has been recommended to use frequencies of 30 to 50 Hz and a pulse width between 0.1 and 0.5 ms for 20-30 minutes per day, five times per week, over 3-4 weeks on the lower limbs, which has been associated with successful outcomes.[9] This study adapted the 2009 research by Mesci et al., which involved complementing an inpatient rehabilitation program with NMES for hemiplegic foot dorsiflexor muscles. The protocol included 20-minute sessions daily, five days a week, for a total of 20 sessions. The proposed mechanism behind this improvement involves enhancing reciprocal inhibition by stimulating the antagonistic muscle and mediating the afferent nerve pathway, thereby inhibiting the spastic muscle and enhancing presynaptic inhibition. This is believed to promote neuroplasticity within the neural network.[12,31] This study found that range of motion (ROM) appears to be more affected than spasticity, possibly due to compliance with the added stretching exercises incorporated with NMES.

On the other hand, this study did not show any statistically significant improvement in lower limb function, as assessed by the 10-Meter Walk Test (10MWT) and the Fugl-Meyer Assessment for Lower Extremity (FMA-LE). This outcome might be attributed to the methodology, as the home-based program did not include task-related or functional activities. Participants were instructed to maintain a stable sitting position while applying NMES. A previous RCT by Shamay *et al*. (2007)[32] demonstrated improved gait velocity in the intervention group that combined electrical stimulation with task-related training, and a study by Sabut *et al*. (2011)[18] using FES on the lower limbs showed reduced spasticity and functional recovery as assessed by FMA-LE.

This study suggests that the home-based NMES program is feasible and well-tolerated in stable ambulatory chronic post-stroke populations. Only one patient dropped out of the study due to a medical condition, rather than intolerance to the program. Furthermore, adherence among completers was excellent, with all but one participant completing all 20 sessions, and that

participant completing 80% of the sessions. No serious adverse events were reported during the study. These findings are consistent with previous feasibility studies conducted in chronic post-stroke populations with upper extremity weakness by Gabr *et al*. (2005)[33] in the Midwestern United States, which showed high participant compliance to home-based ES. Additionally, Noma *et al*. (2014)[19] in Japan reported program completion without any safety issues. Previous studies examining NMES feasibility in critically ill patients in the intensive care unit, acute heart failure patients, and severely obese patients with obstructive sleep apnoea syndrome (OSA) also demonstrated that the interventions were tolerated and feasible when administered by trained therapists.[34-36]

A local multi-center randomized controlled blinded trial is needed to ascertain the effectiveness of the aforementioned outcomes. This study was limited by the COVID-19 pandemic, during which Malaysia implemented multiple national Movement Control Orders. Given that this study involved stable ambulatory chronic post-stroke patients, it is understandable that a significant number of patients avoided hospital visits, thereby making recruitment challenging. Longer follow-up, preferably at 6 weeks, 3 months, and 6 months, is needed to assess the long-term effects of the intervention.

Clinical implications

Previous studies on the feasibility of neuromuscular electrical stimulation were scarce and conducted primarily in developed countries. This study is the first of its kind in Malaysia, a middle-income country, and its findings may be applicable to many other lower- to middle-income countries. This study could lay the groundwork for the development of a structured home-based spasticity program utilizing NMES devices, which are relatively inexpensive, easily accessible, and safe for stroke survivors with mild to moderate localized spasticity, thus avoiding invasive and costly procedures such as repeated injections of Botulinum toxin or oral medications. Establishing a home-based program is crucial in rehabilitation medicine as it empowers patients and reduces the time and financial costs associated with travelling to hospitals.

For limitations, this study acknowledges the significant variation in spasticity levels, ranging from mild (MAS 1) to severe (MAS 3), and recognizes the subjective nature of the assessment, emphasizing the importance of careful interpretation of clinical outcomes. It is also important to consider that patients with longstanding diabetes mellitus (DM) may experience reduced ankle dorsiflexion due to prior tightness in the Achilles tendon, possibly influenced by advanced glycation end product deposition, which is not addressed in this study. This study focused only on improvement in the chronic stage, demonstrating that the use of NMES may still benefit patients at this stage. Understanding these factors is crucial for accurately interpreting clinical outcomes.

In conclusion, this pilot study suggests that a home-based NMES program is both feasible and acceptable for a chronic post-stroke population with lower limb spasticity, evidenced by good adherence, positive feedback responses, and safety. While notable improvements were observed in the range of motion and, to some extent, in spasticity levels, the functional benefits and overall effectiveness remain to be confirmed by future larger randomized controlled trials. Currently, we believe that NMES may be used in combination with or as an adjunct to conventional rehabilitation programs for hemiplegic chronic stroke patients with spasticity.

DISCLOSURE

Conflict of interest: None

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