UNIVERSITY OF MALAYA

FACULTY OF MEDICINE

RESEARCH PROPOSAL

TITLE:

THE FEASIBILITY AND IMPACT OF A HOME-BASED NMES PROGRAM ON POST-STROKE LOWER LIMB SPASTICITY

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CONTENTS

1. LIST OF ABBREVIATIONS

PSS	Poststroke spasticity
UMMC	University of Malaya Medical Centre
NMES	Neuromuscular Electrical Stimulation
MAS	Modified Ashworth Scale
QoL	Quality of Life
PF	Plantarflexors
DF	Dorsiflexor
PC	Pulsed Current
PD	Pulse Duration
Hz	Hertz
s	second
mcs	Microseconds
SPSS	Statistical Package For Social Science

2. ABSTRACT

BACKGROUND: Spasticity is a common complication post stroke. Post-stroke spasticity along with weakness and lack of coordination result in gait abnormalities and problems with upper limb function. This affects stroke survival negatively on health-related QoL, affecting the caregiver and is a socioeconomic burden. Treatment options of spasticity includes physical therapy, ankle-foot orthosis, oral medications; chemodenervation with botulinum toxins, phenol, or alcohol; intrathecal baclofen, and surgical interventions. Recent treatment options include neuromuscular electric stimulation (NMES), a form of therapy that applies electrical currents to produce contraction of innervated muscle by depolarizing local motor nerves. Currently, there are wide varieties of devices delivering NMES, including battery-operated, portable devices. The purpose of this study is to evaluate the feasibility and acceptability of homebased NMES program on lower limb spasticity following stroke. We also like to assess the impact of the program to lower limb spasticity. To date there is no such research available in Malaysia.

OBJECTIVES:
1. To evaluate the feasibility and acceptability of home based NMES program.
2. To assess the impact of home based NMES program in post stroke spasticity (spastic ankle plantarflexors)

METHOD : Single arm prospective cohort intervention study. Participants are patients (post stroke >6months) with ankle plantarflexors spasticity Modified Ashworth Scale (MAS) 1+ to 3. Patient will receive homebased NMES for 20minutes, 5days a week for 4 weeks with stretching exercises while they resume their usual conventional rehabilitation program. NMES dose: Biphasic pulsed current, 50Hz, pulse width 400μs, ON:OFF 10:20s with amplitude individual maximum tolerated to achieve ankle dorsiflexion, with electrodes at common peroneal nerve and motor point of tibialis anterior muscle. Patient will receive NMES treatment in sitting position with sole contact with the floor. Feasibility is determined by retention and compliance rates; acceptability by structured questionnaire at the end of study and the impact is determined by outcome measure of plantarflexors MAS, Modified Tardieu Scale, dorsiflexor strength and 10 meter walking test.

3. INTRODUCTION

3. 1 Research Area

Spasticity is a common complication post stroke. The prevalence of spasticity 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 impact of post stroke spasticity is substantial. Post-stroke spasticity along with weakness and lack of coordination, affects stroke survival negatively on the gait, functional activity and on the health-related quality of life (QoL). It also affects the caregiver on their QoL as increased care that the stroke survivor with spasticity requires, and it is a socioeconomic burden.[5] A study in Sweden reported 4-fold increase in direct costs for patients with stroke with spasticity compared with patients with stroke without spasticity.[6]

There are a number of treatment options for management of spasticity, including physical therapy; the usage of ankle-foot orthosis (AFO), oral medications; chemodenervation with botulinum toxins (BoNT), phenol, or alcohol; intrathecal baclofen therapy; and surgical interventions.[7,8] More recent treatment options include neuromuscular electric stimulation (NMES).[7–9] NMES refers to forms of therapy that apply electrical currents to produce contraction of innervated muscle by depolarizing local motor nerves. Currently there are wide variety of devices deliver NMES, including battery-operated, portable devices [10]. However, NMES as a treatment of spasticity is not widely used in our local population. The purpose of this study is to evaluate the feasibility and acceptability of homebased NMES program on lower limb spasticity following stroke. We also like to assess the impact of the program to lower limb spasticity. To date there is no such research available in Malaysia.

3.2 Research Questions

1. Does home based NMES program is feasible and acceptable for patient with post stroke spasticity?

2. Does home based NMES improve post-stroke spasticity of lower extremities (spastic ankle plantarflexors) assessed clinically and functionally (Modified Ashworth Scale (MAS), Modified Tardieu Scale and walking speed) ?

3.3 Objective

1. To evaluate the feasibility and acceptability of home based NMES program in post-stroke patient with spasticity.

2. To assess the impact of home based NMES program in lower limb spasticity (spastic ankle plantarflexors) following stroke in direct clinical measurement and functionally.

3.4 Significance of this study

1. This is first study in Malaysia that utilizes NMES for lower limb spasticity. The NMES devices are easily available commercially and relatively cheap. By conducting this study, we can assess the feasibility and patient's perceptions of home-based NMES program for post-stroke population and will assist us in further prescription and management of post-stroke patient.

2. It is homebased program. Formulating home-based rehabilitation protocol is substantial for rehabilitation medicine to provide better accessibility, maximize participation and empower patient-driven rehabilitation. Furthermore, with current trend (eg pandemic, logistic issue etc) patient preferred for less frequent hospital visitation; hence strengthening of home-based program is crucial. Thus, we can maintain rehab efficacy with reduced hospital visit and home program.

3. The result of this study will give us further knowledge on the usage of NMES and spasticity management. It enables healthcare professionals to decide on management of spasticity which is possibly less invasive, safe and more cost efficient.

4.0 Literature review

N	Title, Author, year	Type of study, sample size, Population and Methodology	NMES parameters and outcome measures	Result
1.	**The feasibility and acceptability of neuromuscular electrical stimulation to improve exercise performance in patients with advanced cancer: a pilot study**[11] Tamara Windholz, Tara Swanson, Brandy L Vanderbyl and R Thomas Jagoe. BMC Palliative Care 2014	Single arm prospective pilot study N 15-> 10(completed) Intervention: daily NMES at quadriceps Objectives: 1) to evaluate the acceptability and feasibility of a home based NMES intervention in a patients attending the Cancer Nutrition-Rehabilitation Program clinic at the Jewish General Hospital (CNR-JGH) 2) To assess the impact of the NMES intervention on test of physical function.	Frequency: 50 Hz, PD: 300 mcs On/off: 5s on 5 s off intensity was individually to obtain tetanic contraction or maximum tolerated intensity 30min/d, 6 weeks Placement: at vastus medialis oblique distally, midpoint of quadriceps mm belly at proximal Outcome assessment 1. Feasibility - proportion of pt who completed 6/52 intervention, and overall level of adherence (40% cut-off) 2. Acceptability NMES evaluated at the end of 6 weeks by questionnaire. 3. Physical performance measures at baseline and at the end (PS, 6MWT, STC)	The results of the pilot study suggest that NMES is both feasible and acceptable in a mixed group of patients with cancer, most of whom had poor performance status. Does not demonstrate that NMES leads to improved physical functioning in cancer patients with poor performance status, may be due to marked heterogeneity in terms of medical status and physical functioning; and small sample.
2.	**Feasibility of neuromuscular electrical stimulation in critically ill patients**[12]	Prospective cohort study (N 50) To investigate the feasibility of NMES in eliciting a muscle	NMES session for 20min during 5 days per week + standard PT during the stay (positioning, chest PT, ROM and cycling in bed according to pt)	Critically ill patients having sepsis, edema, or receiving vasopressors were less likely to respond to NMES with an

	Johan Segers, PT, MSc a, Greet Hermans, MD, PhD b, Frans Bruyninckx, MD, PhD c, Geert Meyfroidt, MD, PhD d, Daniel Langer, PT, PhD a, Rik Gosselink, PT, PhD a Journal of Critical care, 2014	contraction of the QF in critically ill patients and safety.	NMES session is given in slowly increasing intensitiy and pulse duration in graded fashion to achieve favourable contraction (maximal 80mA and 500 mcs) Outcome measure: 1) Feasibility --> Assessing responder (contraction 4-5) or non responder (contraction 1-3) and the factors affecting it: i- level of consciousness ii- Level of edema iii- Sepsis iv-medications 2) Safety: cardioresp response (HR, BP, O2Sat, breathing) skin response	adequate quadriceps contraction. Neuromuscular electrical stimulation is a safe intervention to be administered in the ICU.
3.	**Does electrical stimulation reduce spasticity after stroke? A randomized controlled study**[13] Amir H Bakhtiary and Elham Fatemy Clinical Rehabilitation, 2008	RCT N 40 (20 intervention, 20 control) 1) Bobath + NMES 2) Control: Bobath Patient with ankle plantarflexor spasticity (does not mention duration post stroke)	Faradic type PC Frequency 100Hz pulse stimulation PD: 100mcs, On:off 4:6, no ramp time supramaximal (25% over the intensity needed to produce maximum contraction of muscle) 9 minutes daily For 20 session Electrodes: cathode on the tibialis anterior muscle via and anode over the fibula head Outcome measures: 1) Passive ankle joint DF range of motion, 2)DF strength test, 3) PF muscle tone by Modified Ashworth Scale (MAS) 4) soleus muscle H-reflex.	Improvement were greater in treatment group: 1) Lower PF spasticity (MAS) in combination group - 1.6 versus - 1.1 in the Bobath group 2) Higher ankle DF ROM in the combination group Vs in the Bobath group = 11.4 vs 6.1 3) Higher DF strength in combination group (0.7 vs 0.4)
4.	**Functional electrical stimulation of dorsiflexor muscle: Effects on dorsiflexor strength, plantarflexor spasticity, and motor recovery**	Prospective interventional study. N 51 (27 intervention, 24 control) 1) Conventional rehab program (CRP) + EMS 2) CRP only	Waveform NR Frequency 35Hz PD 280 mcs Stimulation timed to the gait cycle by using a heel switch placed in the shoe, causes ankle dorsiflexion in the swing phase of gait)	Therapy combining EMS and conventional rehabilitation program was superior to a conventional rehabilitation program alone, in terms of: 1) reducing spasticity, - 1.1 vs - 0.5

	in stroke patients[14] Sukanta K. Sabut , Chhanda Sikdar , Ratnesh Kumar and Manjunatha Mahadevappa NeuroRehabilitation, IOP Press 2011	>3months post stroke with hemiplegia (unilateral drop foot) and able to walk at least 10m without assistance. Not contracted.	Amplitude set to produce muscle contraction within patient's comfort. Duration: 20–30min 5 days a week, for 12 weeks. Electrode: common peroneal nerve as it passes over the head of the fibula and the motor point of tibialis anterior. Outcome measures: 1) PF spasticity measured by MAS 2) DF strength 3) Active/passive ankle joint dorsiflexion ROM 4) Lower-extremity motor recovery by FMA scale. @0 and week 12.	2) improving DF ROM and strength 3) lower extremity motor recovery in stroke patients.
5.	**The effects of neuromuscular electrical stimulation on clinical improvement in hemiplegic lower extremity rehabilitation in chronic stroke: A single-blind, randomized, controlled trial**[15] Nilgun Mesci, Ferda Ozdemir, Derya Demirbag Kabayel & Burcu Tokuc Disability and Rehabilitation 2009	RCT N 40 (20 intervention, 20 control) Intervention: inpatient CRP + NMES Control: inpatient CRP Hemiparesis due to stroke >3 months, mobility of ankle to permit at least neutral position, MAS <4	Biphasic PC wave Frequency 50 Hz Pulse width 400 mcs On:off: NR Intensity: fully contracted muscle without discomfort or pain. Duration 20min 5 days, 4 weeks Pt position: sitting position and to keep their soles of their feet in contact with the floor. Electrode: positive active electrode right below the fibular head where the peroneal nerve is going through; and the negative electrode was positioned on the midpoint of the tibialis anterior muscle on the front side of the leg. Outcome measures: 1. Ankle passive DF ROM 2. Spasticity MAS 3. Neurophysiological improvement in the lower extremities in Brunnstrom Stage (BS) 4. Functional Independence Measurement (FIM).	Improvement were greater in treatment group in all outcome measures. 1) ankle DF ROM (6.25 vs 1.0) p=0.000 2) decrease in the MAS -1.2 vs -0.15 (P=0.000) 3) increase in the lower extremity BS 0.8 vs 0.25 (p=0.005) 4) improvement in the Rivermead leg and trunk scores p= 0.004) improvement in the FIM motor subscore (p =0.018)

			5. Rivermead Motor Assessment Scale 6. Functional Ambulation Categories (FAC)	
6.	**Transcutaneous Electrical Nerve Stimulation Combined With Task-Related Training Improves Lower Limb Functions in Subjects With Chronic Stroke**[16] Shamay S.M. Ng, PhD; Christina W.Y. Hui-Chan, PhD 2007	single-blinded, stratified, randomized, controlled trial. N= 88 4 groups: (1) TENS, (2) TENS +TRT, (3) placebo TENS +TRT (4) no treatment (control) 1 year post stroke and able to walk 10 m unassisted with or without walking aids, and Composite Spasticity Score of at least 10 or more in their ankle PF (moderate spasticity)	Square PC Frequency: 100Hz PD: 200mcs Intensity: 2 to 3 times sensory threshold Duration: 60minutes 5 days a week for 4 weeks. Home program with 8 outpatient sessions. Placement: 4 acupuncture points Outcome measurements: 1) Composite Spasticity Scale, 2) peak torque ankle dorsiflexors and plantarflexors recorded with a load cell mounted on a custom- built foot frame 3) gait velocity (GAITRite) @ baseline, after 2 and 4 weeks of treatment, and 4 weeks after treatment ended	Both TENS (TENS and TENS+TRT) groups showed earlier and significantly greater of reduction in PF spasticity as measured at week 2 Combining TENS with TRT improved outcome measures significantly more than TENS alone, PLBO+TRT, or no treatment. Improvements can even be maintained 4 weeks after treatment ended
7.	**Effects of Electrical Stimulation in Spastic Muscles After Stroke Systematic Review and Meta-Analysis of Randomized Controlled Trials**[9] Cinara Stein, MSc; Carolina Gassen Fritsch, Ft; Caroline Robinson, MSc; Graciele Sbruzzi, DSc; Rodrigo Della Méa Plentz, DSc American Heart Association, 2015	Systematic review 4 electronic databases (5066 titles) 29 randomized clinical trials were included with 940 subjects. → UL and LL	The primary outcome extracted was spasticity, assessed by the Modified Ashworth Scale, and the secondary outcome extracted was range of motion, assessed by Goniometer	In this review, the usage of NMES with a frequency between 30 and 50 Hz and a pulse width between 0.1 and 0.5 ms for 30 minutes 5 times per week for 3 to 4 weeks were associated with successful results.

5. Methodology:

5.1 Study Design

Single arm prospective cohort intervention study. Patient with PSS recruited and will apply NMES to the lower limb at home in addition to their daily stretching exercises of their plantarflexion. They may also resume their conventional outpatient therapy session.

5.2 Setting

- Recruitment: Specialist clinic and therapy areas of Department of Rehabilitation Medicine, UMMC.
- Intervention: Home setting

5.3 Study population

- Participants who are attending Rehabilitation Medicine Specialist clinics and therapy areas that fulfill the criteria will be screen for eligibility and recruited.
- Demographics of participants including age, sex, race, dominant hand, etiology of stroke (ischemic/hemorrhagic), side of hemiparesis will be recorded.

5.4 Inclusion criteria includes:

- Post stroke (hemorrhagic or ischemic) with ankle plantarflexor (gastrocnemius and soleus) spasticity MAS 1+ to MAS 3
- Post stroke more than 6 months
- > 18 years old
- Able to ambulate 10 meter either independently or aided (single point stick or quadripod)
- Compliant to outpatient therapy.
- Minimal cognitive (MMSE> 24) and minimal sensory impairment
- Stable neurological and medical condition

5.5 Exclusion criteria

- Introduction or changes in anti-spastic medication dose within 3 months or during study period
- Receiving intervention for spasticity (eg BoNT or serial casting) within 3 months or during research period.
- New neurological condition/disease
- Presence of contraindications to NMES, which is[17]:
    - Pregnancy
    - Malignancy
    - Presence of electronic implant eg 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 person with untreated hemorrhagic disorder
- Damaged or skin diseases at the affected lower limb

5.6 Sample Size

Consistent with the feasibility design, no formal sample size calculation was undertaken; rather a target sample of 20 participant was deemed sufficient to provide preliminary data required to test our feasibility study aim.

Furthermore from literature review, Bakhtiary et al reported improvement of plantarflexor spasticity (MAS) in intervention group - 1.6 (SD 0.5) versus - 1.1 (SD 0.31) in control group. Thus the effect size is 0.75, and for an alpha of 0.05 and power of 0.8, sample size of 23 each arm is needed (not considering the attrition rate).

5.7 Intervention, dose and mode of administration[15]:

- It is a home-based NMES applications over the lower limb with plantarflexor spasticity using a commercially available consumer NMES machine.
- Each patient will get a pair of new electrodes.

- Dose of NMSE:
  - NMES waveform: biphasic PC
  - Frequency 50Hz, pulse width: 400μs, ON:OFF 10s:20s
  - Current amplitude: individual maximum tolerated to achieve ankle dorsiflexion.

- Electrode placement (transcutaneous surface electrode):
  - 1 electrode over the common peroneal nerve outlet (below the fibular head),
  - 1 electrode over motor point of tibialis anterior or both tibialis anterior and peronei muscle.

- Body and limb position: Patient sitting with the sole in contact with the floor, and try for active dorsiflexion during stimulation.

- Duration: 20 minutes per session daily, 5 days a week, for 4 weeks (total 20sessions)

- Compliant is monitored by daily logbook (Appendix 1)

5.8 Outcome measures

- Primary Outcome:
  1) Feasibility as assessed by proportion of patients who completed the program, and overall level of compliant (retention and compliance rates)

  2) Acceptability as evaluated at the end of the intervention by brief structured

questionnaire developed for this study using 5 point Likert scale (Appendix 2)

- Secondary Outcome:
  1) Clinical measurement of spasticity and functional outcomes:
     a. Modified Ashworth Scale (MAS)
     b. Modified Tardieu Scale (R1 R2 of ankle dorsiflexion)
     c. Ankle dorsiflexion muscle strength
     d. 10 meter walking test

5.9 Study Flow Chart

1) Screening - Inclusion/exclusion criteria application to patients attending Rehabilitation Medicine Specialist clinic and therapist area

2) Consent - Explanation of study, Patient Information Sheet and Written Consent

3) Pre-intervention assessment and familiarization session
- Pre-intervention assessment per outcome measures (MAS, Modified Tradieu Scale, strength, and 10MWT)
- Teaching patient (with or without family member) application of NMES
- Trial of a 20 minutes session

4) Intervention: Home-based NMES program for 4 weeks
- A NMES device will be loaned to patient throughout the study period
- A new pair of self-adhesive electrodes will be given to patient
- Pre-setting NMES dose: Frequency 50Hz, pulse width: 400µs, ON:OFF 10s:20s
- daily logbook

5) Completion of intervention
- Submission of logbook and NMES machine
- post intervention assessment as per outcome measures (MAS, Modified Tradieu Scale, strength, and 10MWT)
- Post intervention questionnaire

5.10 Data Analysis

Data from this study will be analyzed using Statistical Package for Social Science (SPSS) software.

- Comparison between participants who did and did not complete the study and the compliance rate will be performed using unpaired t-test and Fisher's exact test for continuous and categorical variables respectively.
- Improvement spasticity MAS (grading) – *paired t-test*
- Improvement in ankle dorsiflexion ROM (degree) – *paired t-test*
- Ankle dorsiflexion muscle strength (grading) – *paired T-test*
- *10 meter walking speed (ms-1) – paired t-test*

6.0 Strength and Limitation

Strength

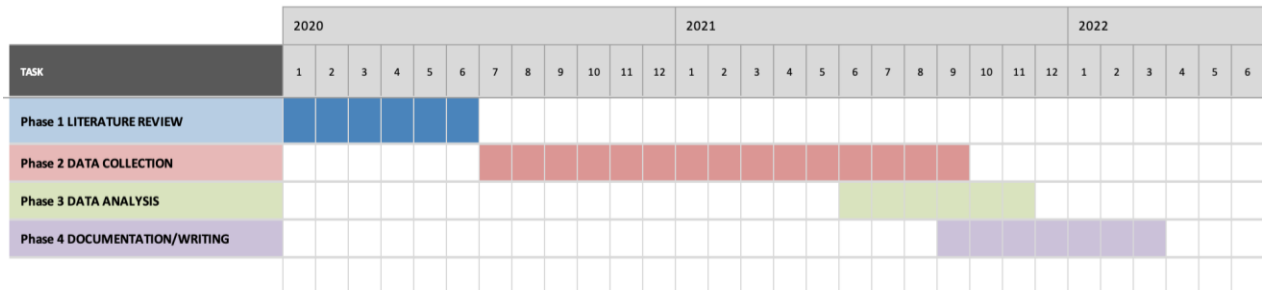
- No previous published study in Malaysia looking at NMES application for reducing spasticity post- stroke.
- Easily available equipment commercially and relatively cheap and safe.
- Study conducted in stroke population therefore adequate number of samples can be recruited.

Limitation

- Resource and funding; it will be self-funded by main investigators.
- Equipment handling and maintenance; risk of faulty equipment which could limit the research progress.
- Single centre study

7.0 Timeline

Gantt Chart



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Appendix 1

Patient's Feedback Questionnaire

R/N:…… Date:……..

	General acceptability and satisfaction	1= Strongly Disagree	2 = Disagree	3 = Neutral	4 = Agree	5 = Strongly Agree
1.	Using the NMES for 4 weeks is acceptable					
2.	Using NMES for 20 minutes a day is acceptable					
3	Using NMES had a positive impact on my lower limb spasticity					
4.	Using NMES had a positive impact on my ambulation					
5.	I would continue/repeat the NMES program after the study					
6.	I would recommend this program to my colleagues/other patients					
7	Overall, I think the homebased NMES program is a good intervention					
8.	I would consider buying the device if the price is affordable					

	Device's operation experiences.	1= Strongly Disagree	2 = Disagree	3 = Neutral	4 = Agree	5 = Strongly Agree
9.	The NMES device is simple to use					
10.	Most of the time I can handle the device independently.					
11.	It is easy to put on the surface electrode to the lower limb.					
15.	I can use the surface electrode independently					

	While using the NMES, I have experience….	1= Never	2 = Rarely	3 = Sometimes	4 = Often	5 = Always
16	Pain					
17	Discomfort					
18	Skin irritations/ burns					
19	Muscle fatigue					
20	Others:					

Do you have any other comment or concern?

_____

_____

Appendix 2

HOME-BASED NMES PROGRAM LOG SHEET

Name: _____

RN/ IC: _____

Period: _____to _____

Week 1:

No	Date	Time start	Time end	NMES intensity	Stretching	Notes
1.						
2.						
3.						
4.						
5.						

Outpatient therapy session: Yes/ No

Date:
Time: From _____to _____
Place:

Week 2

No	Date	Time start	Time end	NMES intensity	Stretching	Notes
1.						
2.						
3.						
4.						
5.						

Outpatient therapy session: Yes/ No

Date:
Time: From _____to _____
Place:

Week 3

No	Date	Time start	Time end	NMES intensity	Stretching	Notes
1.						
2.						
3.						
4.						
5.						

Outpatient therapy session: Yes/ No

Date:
Time: From _____to _____
Place:

Week 4

No	Date	Time start	Time end	NMES intensity	Stretching	Notes
1.						
2.						
3.						
4.						
5.						

Outpatient therapy session: Yes / No

Date:
Time: From _____to _____
Place: