CHI Institute for Research and Innovation

[redacted]Protocol Title, Version Number, and Version Date

Protocol Version Number:3

Protocol Version Date: 5/24/22

IRBNet ID: 1643900

Investigators

Principal investigator: Courtney Ellerbusch, PT, DPT
Cell-303-905-8272
Secondary investigator: Dr. Julie Seibert, MD
Work-303-730-2883

[redacted]Funding Source

NeuFit is funding costs associated with IRB review board, Statistician fees and Hoffman's reflex testing. The primary investigator is not accepting any personal compensation.

[redacted]Objectives and Hypothesis(es)

The hypothesis we hope to test is if treating individuals with multiple sclerosis (MS) at the peripheral nervous system (PNS) level in golgi tendon organ and muscle spindles using a direct current through the NeuBie electrical stimulation device can inhibit spasticity and improve functional mobility in clinically significant measures. There are two significant structures within the PNS that have a significant impact on spasticity level closely monitored by the central nervous system (CNS). These structures are muscle spindles within the body of all skeletal muscle and golgi tendon organs within the muscle tendons. These structures when functioning normally within a fully intact neurological system are protective against over stretch in muscle, or tendon and bone injury causing reflexive counterforce or dropping a weight that is too heavy. In an individual with MS the CNS is over-protective and causes the threshold for stretch reflex and muscle tightness to be set lower than normal. This inhibits normal movement and causes abnormalities in posture, stiffness and at times joint contractures. In this pilot study we hope to assess the ability for the direct current of NeuBie, which creates mechanoreceptor inputs and lengthening at the sarcomere level of muscle and joints in the spine and lower extremity, to alter the proprioceptive PNS at muscle spindle and GTO level with a change in CNS over-guarding during the treatment and after the treatment. If we are able to create normalized stretch and muscle tension at the PNS level, it may be possible to create temporary or sustained CNS level changes. This would allow the amount of stretch and tension at the PNS level to be normalized and possibly reduce spasticity. If this theory is accurate, we may be able to increase access to

normalized movement, strength and functional ability in individuals with neuro-compromise.

Approximately 66%[6] to 84%[1] of individuals with multiple sclerosis experience various levels of debilitating spasticity[6] limiting freedom of movement at ankles, knees and hips causing deficits in ambulation, weakness from disuse of muscles not accessible due to spasticity. Per the North American Research Committee on Multiple Sclerosis[1], a survey was conducted on spasticity prevalence and results show 84%[1] have some degree of spasticity from mild to incapacitating. Spasticity pathophysiology is complex and not completely understood with higher levels of incapacitating spasticity reported in this survey by those who were male, disabled and unemployed[1], indicating that psychosocial and subjective variables are significant. The pathophysiology currently best understood demonstrates an imbalance between inhibitory dorsal reticulospinal tract (RST) fibers and excitatory bulbopontine tegmentum. RST neurons receive direct somatic, vestibular, tectal, cerebellar and motor excitatory input and are scattered in the ventral and lateral spinal cord columns intermingled with propriospinal fibers[1]. The peripheral Golgi tendon organ of muscle tendon and muscle spindle intrafusal fibers ubiquitous throughout the musculoskeletal system have direct monosynaptic connection to these central nervous system propriospinal fibers and heavily influence the degree of spasticity and overactive stretch reflexes[1,10].

[redacted]Those who deal with all levels of spasticity use compensatory movement strategies causing altered arthrokinematics and have loss of strength, balance and efficient muscle use with postural changes. Spasticity management has been studied and treated from a pharmaceutical standpoint with some improvements but often side effects including fatigue, muscle weakness and cognition limit dosing in oral Baclofen, Dantrolene Sodium, Tizanidine and Benzodiazepines[1]. Marijuana especially in form of cannabinoids shows mixed evidence for spasticity improvement and is a growing area of interest. There is a growing CBD interest in the MS population due to known reduction of CNS neurodegeneration in animal MS studies and no significant negative side effects with possible mild to moderate improvement in spasticity levels[1]. Therapy interventions offered include frequent stretching especially of muscles that cross two joints including lumbricals, hamstrings, gastrocnemius and iliopsoas; light stroking over lower limbs demonstrated a 30% decrease in H-reflex amplitude lasting even 30 minutes after treatment; muscle cooling was shown to reduce muscle stretch activity and clonus; Armutlu et al. Reported significant reduction in plantar flexor spasticity in 10 patients with MS using high-frequency (100Hz) TENS for 20min daily for 4 weeks. Reduction noted on Modified Ashworth Scale (MAS), electrophysiologic

measurements and the AI; and serial casting performed over a 9-day period with cast changes every 3 days demonstrated reduced spasticity levels[1].

Background/Scientific Rationale and Significance

The NeuFit company offers a NeuBie EMS product with a direct current using high fidelity audio equipment to decrease intensity of the treatment noxious stimulus and protect skin integrity from burns or intolerable pain. This system uses an exponential wave pattern to mimic the natural pattern neurologically to lengthen fibers of the sarcomere and engage force velocity of muscle with minimized protective co-contraction of nearby muscle groups[9]. The golgi tendon and muscle spindles code for joint position and muscle/tendon stretch with 66% of fibers being intrafusal. Impacting these structures has direct impact on reticulospinal tract (RST) fibers and proprioceptive central fibers modulation of levels of spasticity. However, finding effective means to impact these areas is difficult. The NeuBie direct current is designed to improve positioning of these stretch receptors. As discussed within the paper hypothesis, the theory is that this may improve spasticity levels as well as agonist strength enough to create long term, significant functional improvement.

Dr. Terry Wahls who has MS and has studied and marketed a protocol for MS treatment, promotes this product and has a home unit she uses daily to control her own MS symptoms and gain strength. Currently there is no research study conducted on the effects of the NeuBie direct current treatment combined with exercise and ramifications of spasticity in multiple sclerosis. There have been only a few studies conducted with quantitative spasticity measures mostly with FES and NMES targeting tibialis anterior and quadriceps to lessen plantar flexor spasticity[10] in spinal cord injury (SCI) and hemiplegia. In the SCI study Mirbagheri et al. observed decreases in intrinsic and reflex dynamic stiffness in all 4 subjects studied over a 16-month period. Robinson et al. stimulated quadriceps muscle pulse duration 500, 20 Hz and amplitude of 100 with spasticity quantitatively reduced immediately after stimulation but return of baseline spasticity level when measured 24 hours later[10]. Levin and Hui-Chan assessed sensory level stimulation of the common peroneal nerve for a total of 15, 60 min sessions for 3 weeks in people with hemiplegia using pulse duration 125 continuously at 99Hz and observed inhibition of H-reflex at soleus, increase in dorsiflexion voluntary force and reductions in stretch reflex at triceps surae[10].

The NeuFit method of treatment allows the recipient to voluntarily concentrically or eccentrically activate muscles while receiving the direct current passive eccentric input. In order to assess the feasibility of this papers' hypothesis we will perform a pilot study of up to 9 individuals with MS in the greater Denver metro area. At the time of the study we are in a global pandemic and the safest path

forward is a design with one patient receiving treatment at a time for infectious precautions.

[redacted]Inclusion and Exclusion Criteria

Dr. Julie Seibert will screen all potential participants for the following inclusion and exclusion criteria prior to making a referral for participation in the study.

Inclusion criteria

1. Greater than 18 years old (no upper age limit)
2. Physician diagnosed MS (As stated in Rooney S, et al. Disabil Rehabil. 2019, stage of MS did not impact individuals from making neuromuscular or functional gains. All stages of MS will be eligible)
3. Physician clearance to participate
4. Unable to ambulate more than 150 feet at a time and unable to ambulate within the home or outside the home without the use of an assistive device.
5. BLE MMT in hips, knees and ankles <=3/5
6. Modified Ashworth assessed spasticity levels 1-4

Exclusion criteria (based on recent FES studies Backus 2017 and Szecsi 2009)

1. Co-morbidities in cardiovascular disease (myocardial infarction in past 1-year, unstable angina, CHF, h/o arrythmia, h/o CVA or TIA in past year, uncontrolled hypertension)
2. History of epileptic seizures
3. Lower Motor Neuron disease
4. Existing pacemaker, defibrillator or other implanted device (other than baclofen pump)
5. Unstable long bone fractures of lower limb or trunk
6. Allergies to surface electrodes or conductive gel
7. Pregnancy or actively seeking to become pregnant

[redacted]Vulnerable Populations

No vulnerable populations to be studied.

[redacted]Number of Subjects

This will be a pilot study using a series of up to 9 case studies for up to 9 participants. All studies will be completed entirely from the subject's home with CSHRI IRB oversight.

[redacted]Recruitment Methods

Dr. Julie Seibert will recruit participants who meet inclusion and exclusion criteria from her database. If Centura Health at Home receives a referral who may be a fit and is interested in participation, we will have this participant screened through Dr. Siebert's office to ensure fitness and safety to participate. Participants will be contacted by telephone or mail from Dr. Seibert. Only approved researchers are allowed to participate in study related activities.

Telephone Script:

"Hello Mr or Mrs. X, my name is Courtney Ellerbusch and I am a doctor of physical therapy who works for Centura Health as a home health physical therapist with a personal interest in the multiple sclerosis population. [Dr.Seibert, a local neurologist specializing in multiple sclerosis] or [Our agency has identified you] as a potential candidate to participate in a small Pilot study to assess an electrical stimulation's device effectiveness on your multiple sclerosis symptoms. Are you interested in being considered as a participant? If so, Dr. Seibert will review your health record to ensure you fit our patient parameters for safe participation."

If the answer is "Yes"- Arrangements will be made for the potential participant to have an appointment with Dr. Seibert to sign the consent form, objective measures and assessment along with a Hoffman's reflex assessment by Dr. Dan Koontz. Dr. Seibert will generate a referral to Centura Health at Home for the primary investigator to evaluate and treat per the study parameters.

If the answer is "No"- The individual will be thanked for their time and not contacted again for purposes of study participation.

Mail Prose:

DATE: X

TO: Potential Participant X

PROJECT TTTLE: [1643900-1] A Pilot Study of NeuBie, a direct current electrical stimulation device, to inhibit lower extremity spasticity levels and normalize muscle functional use during transfers and ambulation in individuals with multiple sclerosis.

Dear "X",

Dr. Courtney Ellerbusch, a field staff physical therapist from Centura Health at Home, and Dr. Julie Siebert from Colorado Neurodiagnostics are formally contacting you to request your participation in a Pilot study for multiple sclerosis. There is no pressure to participate and whether or not you choose to be involved, no changes will occur to your healthcare or insurance standings.

The format of this study has undergone rigorous review for safety and compliance parameters with the CommonSpirit Health Research Institute Institutional Review Board (CSHRI IRB) for your safety.

The study will require up to 10 weeks of various form of appointments, testing and active therapy participation. Specifically, you will need an initial appointment with Dr. Seibert to understand and sign our consent form as well as initial testing in EDSS, then you will be arranged in same office on same day to see Dr. Dan Koontz for H-reflex testing. Once these steps are complete, you will be referred by Dr. Seibert to Centura Health at Home to work with Dr. Courtney Ellerbusch for visits 3 times per week over a period of 6 weeks. She will come directly to your home for all portions of treatment and assessments. Dr. Ellerbusch will perform testing and treatment using an FDA approved direct current electrical stimulation device and exercise, stretches and a form of manual therapy known as primary and secondary activations. Once the treatment portion of the study is complete you will need to have a follow-up appointment with Dr. Seibert and Dr. Koontz for re-testing.

1. If you would like to consult further prior to making a decision please contact the primary investigator directly:
    a. Dr. Courtney Ellerbusch, PT, DPT
       303-905-8272
       courtneyellerbusch@centura.org

2. If you are certain you would like to be a participant, please call Colorado Neurodiagnostics directly to arrange an initial appointment with Dr. Julie Seibert. Please mention your interest in the Pilot study participation when calling.
    a. Colorado Neurodiagnostics (coneurodiagnostics.com)
        i. 303-730-2883

Thank you for your time and consideration.

Sincerely,

Courtney Ellerbusch, PT, DPT

[redacted]Study Timelines

- All participants will be referred through Dr. Seibert. We will plan to start with only one participant for the first case study to ensure all steps completed as planned. Then the second case study is to begin as soon as the first one is completed and on until up to 9 case studies are completed. Dr. Ellerbusch will start with one participant at a time, then once all steps completed will be open to treating to 2 study subjects at a time.
- Depending on timeline for IRB approval and Centura approval we hope to begin this study in the Spring of 2021 and depending on

number of subjects and timeliness of finishing one case study and starting the next we'd hope to complete the study by Winter of 2021.

[redacted]Study Endpoints

[redacted]The primary study endpoint of this pilot study to assess if decrease in spasticity for individuals with MS is possible during NeuBie direct current treatment and for any length of time after treatment to further learn if this correlates to improvement in functional gait and transfers. The listed subjective and objective data points are selected to capture this endpoint.

[redacted]Procedures Involved

Study methods:

1. Treatment portion of study:
2. The physical therapist will implement manual activation techniques combined with NeuBie and PT exercise interventions 3 times per week for 6 weeks.
   - i) Use of Treatment table with manual activations to underactive, spastic or limited in sensory muscles/regions (The PT will consider primary and secondary activations to strengthen neural pathways maximally)
   - ii) NeuBie Mapping mode scanning process with electrode placed on thoracolumbar space and second sponge electrode scanning for:
     - (1) Spots that stimulate movement they couldn't do before per initial assessment
     - (2) Spots that allow movement which is a greater range than available before per initial assessment
     - (3) Spots that lead to decreased spasticity (turn up amplitude and have participant work through the threat response then repeat)
     - (4) Diminished sensation areas – drive signal to increase sensory nerves and become metabolically active. Consider knee, hip and ankle joints as these are neurologically rich.
   - iii) Train using physical therapy exercises with Neubie in training mode and Hz current adjusted for tolerance, ability to work through or decrease spasticity in (500 Hz) in the following areas (spasticity, contraction, dead or diminished spots and hot spots) as tolerated but remove if participant is displaying signs of fatigue
     - (1) Spasticity areas – 500Hz – adjust amplitude to 7/10 discomfort and Pt works through spasticity with assist from PT as needed. The muscle that oppose the spasticity (agonist) will be considered for 40Hz current adjusted no higher than 7/10 discomfort with movement patterns out of the spasticity.
     - (2) Contraction areas -500Hz – adjust amplitude to 7/10 intensity and participant works with contracting muscle without altered kinematics or co-contraction. The muscle that oppose the spasticity (agonist) will be considered for 40Hz current adjusted no higher than 7/10 discomfort with movement patterns out of the spasticity.

(3) Dead/diminished areas – establish a baseline amplitude for sensation and leave signal on at this amplitude. Over time assess if the amplitude for sensation is decreased demo return of sensation.
(4) Hot spots – assess if the same amplitude over these areas which creates high level of discomfort becomes less uncomfortable over time as a sign of increased neurological resiliency.

iv) Continue with electrodes in place and apply with functional training in high kneeling, sitting, transfers, standing static, standing dynamic closed chain, standing dynamic open chain, gait and movements available in LE/core
v) Progress participantin sitting balance unsupported, sit to stand, standing balance static and dynamic and in gait
vi) If participanttolerates less amplitude signal next visit while working through spasticity or contraction, they are in neurological fatigue and consider master re-set, sensory inputs, stretches and more gentle approach for active recovery

If participant was not receiving this intervention, they would receive traditional physical therapy in stretching, therapeutic exercise training open chain and closed chain, transfer training, gait training and balance training working within limits ofparticipant's spasticity levels.

Participants in this study will participate in the listed interventions for 6 weeks. Outcome measures objective and subjective will be collected at the beginning and end of the study.

1. EDSS – Dr. Seibert performs (https://www.mstrust.org.uk/a-z/expanded-disability-status-scale-edss)
2. Hoffman's Reflex – Dr. Dan Koontz performs (Dr. Koontz performs test only, then gives results to investigators.) (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC522151/)
3. 12 item MS walking scale –Dr. Ellerbusch performs https://www.sralab.org/sites/default/files/2017-07/msws-eng.pdf
4. Manual Muscle test – Dr. Ellerbusch performs
5. Modified Ashworth test – Dr. Ellerbusch performs https://www.sralab.org/sites/default/files/2017-06/Modified%20Ashworth%20Scale%20Instructions.pdf
6. 25 foot walk test – Dr. Ellerbusch performs https://www.nationalmssociety.org/For-Professionals/Researchers/Resources-for-Researchers/Clinical-Study-Measures/Timed-25-Foot-Walk-(T25-FW)
7. Timed up and Go –Dr. Ellerbusch performs https://www.cdc.gov/steadi/pdf/TUG_test-print.pdf

8. Multiple Sclerosis Impact Scale (MSIS-29) – Dr. Ellerbusch performs https://www.mstrust.org.uk/sites/default/files/MSIS-29.pdf

[redacted]Data and Specimen Banking

No specimen collected.

[redacted]Data Analysis Plan

The data in this small sample will be reported using descriptive statistics such as number and percent. Measures of central tendency such as mean, median and mode will be analyzed for trends or results. A third party, Dave Drachman, will provide statistical analysis based on psychometric data and objective date with minimally clinically significant changes for these measures. Dr. Julie Seibert will assess and analyze her own data measures. Dr. Dan Koontz will assess Hoffman's reflex test and provide the results to Dr. Seibert and Dr. Ellerbusch. Dr. Koontz does not have a role in the study beyond making the Hoffman's reflex test results available for use in this study. All study results will be made available to Dr. Ellerbusch, lead investigator. I will pass these results to Dave Drachman. All of the participants 18 HIPAA identifiers will be protected using a numerical system per participant in all transmissions.

[redacted]Provisions to Monitor the Data to Ensure the Safety of Subjects

Dave Drachman, upon collection of results the protocol will be updated to when each case study with an individual is complete. I will also review the collected data after each 6-week period of working with the subject.

[redacted]Withdrawal of Subjects

All participants will participate on an at will basis and will be allowed to discontinue at any time. If a participant is participating and develops an exclusion criterion such as pregnancy they will be withdrawn from the study per the disclosure notice. Forty-eight hours in advance of discharge from home health physical therapy and termination of the study, participants will sign the Notice of Medicare Noncoverage form. If a participant participates in part but not all of the study, data will be collected and stored to be determined in collaboration with statistician at what level their data can be used for *analysis.*

[redacted]Risks to Subjects

This study carries very low risk to subjects. Possible risks include fatigue from the NeuBie device and exercises used. Subjects with comorbidities that would make participation unsafe will not be included in the study.

Potential Benefits to Subjects

Relaxation of muscle spasm
Decrease in spasticity
Prevention or retardation of disuse atrophy
Increasing local blood circulation
Neuromuscular re-education
Maintaining or increasing range of motion
Symptomatic relief and management of chronic pain

Sharing of Results with Subjects

Once the subject's participation and all required testing is complete, he or she may have access to their objective and subjective before and after test measurements. These results will be printed and mailed to the participant's home address upon request.

Setting

Participants in study will be selected based on inclusion and exclusion study criteria by Dr. Seibert from her patient list. Any direct referrals to Centura Health at Home who may be candidates based on diagnoses and appearance to match criteria who are willing will be referred to Dr. Seibert to ensure fitness to participate in study, understanding and signing of consent form and initial testing. The 3 times per week 6-week study treatment visits will be performed at the participant's home.

- Other research procedures performed from Dr. Seibert's office and participants' home.

Resources Available

Courtney Ellerbusch, PT, DPT is a field staff physical therapist for Centura Health at Home with 8 years clinical experience post doctorate. Dr. Julie Seibert, MD is a neurologist for Colorado Neurodiagnostics specializing in Multiple Sclerosis. Garrett Salpeter is the NeuBie founder and director and not performing the study, but he and his team available for consultation during study formation and implementation.

Describe other resources available to conduct the research: For example, as appropriate:

- Dr. Seibert has a large base of patients with Multiple Sclerosis to draw from as potential participants. We hope to study up to 9 participants and this is highly feasible with her list and Centura connections with other local neurologists if needed.
- Courtney Ellerbusch will treat subjects as part of her weekly workload with added time during visits and after visits to ensure

data collection and management handled carefully and well tracked.

- This study will be performed from each participant's home which will vary based on many factors.
- Home Health subjects do have access to social workers, nurses, occupational therapists, CNAs as needed to ensure their needs are met. However, additional therapy would complicate results and participantswill be encouraged to meet additional therapy needs at another time or choose to not participate.
- Direct emails and phone calls to and from Dr. Seibert and Garrett Salpeter to ensure all aspects of protocol communicated clearly, agreed upon and understood. A record of the study design is saved and has been sent to these individuals.

[redacted]Prior Approvals

No prior approvals.

[redacted]Confidentiality

Describe the local procedures for maintenance of confidentiality.

- Data collected will be stored in Dr. Seibert's office and Dr. Ellerbusch's office for 6 years in a file folder securely located.
- Electronic records kept on Centura server.
- Local access to data will be available to Dave Drachman for statistical analysis, Dr. Seibert and Dr. Ellerbusch.
- Receipt and data transmission locally will be managed by Dr. Ellerbusch and Dr. Seibert
- Dr. Ellerbusch will keep written and electronic records of data in her car for transport from field to secure home office.

Data will be kept private and confidential on secure laptop managed by Centura.

Provisions to Protect the Privacy Interests of Subjects

Participants' privacy interests will be protected through HIPAA law and regulation and researchers will not divulge any private information to anyone other than the subject at the end of the study.

Participants will be given opportunity prior to committing to participate and throughout the study to understand the purpose of the study, possible risks and possible benefits along with their roles and responsibilities.

The research team shall be granted access to subjects' medical records, home address, phone number, insurance coverage and all of this will be

kept confidential and used only for the purpose of subject safety as well as fitness to participate in the study.

[redacted]Economic Burden to Subjects

Participants will be responsible for any co-pay insurance cost for visits with Dr. Seibert and home health agency visits at a frequency of 3 times per week for 6 weeks.

[redacted]Consent Process

All subjects will be given a consent form with explanation and review to sign.

- Consent to participate form will be signed from Dr. Seibert's office during initial screening. Informed consent will be obtained prior to any research related screening procedures.
- Subjects will be informed of their right to discontinue participation at any time.

Non-English Speaking Subjects

- Spanish speaking participants are welcome and the primary researcher speaks clinical Spanish.
- If a Spanish speaking subject wishes to participate, oral and written information in their language will be provided. The CryaCom interpreter language line is available for use to ensure communication is understood.

[redacted]Process to Document Consent in Writing

Signed consent forms for Centura Health at Home will be sent via secure Tiger Text to Judy Deherrera of CHAH operations for their record and kept in secure electronic records. This is the standard of practice for Centura Health at Home. Research consent forms will not be sent via Tiger Text. The research consent form will be kept securely in a lock box within the office of Courtney Ellerbusch, PT, DPT.

[redacted]Drugs or Devices

The NeuBie electronic stimulation device will be stored in the office of Courtney Ellerbusch outside of visits, transported in her car to visits and electrodes used by participantwill be kept in the participant's home. All aspects of the device that may come into contact with the subject or home will be sanitized between visits.

References:

1. Brashear A, Elovic E. Spasticity: Diagnosis and Management. In: Shah A, Maitin I ed. *Spasticity Due to Multiple Sclerosis: Epidemiology, Pathophysiology and Treatment*. New York, NY: Demos Medical Publishing; 2011: 341-352.
2. Backus et al. Outcomes After Functional Electrical Stimulation Cycle Training in Individuals with Multiple Sclerosis Who Are Nonambulatory: A Pilot Study. International Journal of MS Care. 2017.
3. Etoom et al. Effectiveness of Physiotherapy Interventions on Spasticity in People with Multiple Sclerosis: A Systematic Review. American Journal of Physical Medical Rehabilitation. 2018.
4. Wahls, T., Reese, D., Kaplan, D., Darling, W. Rehabilitation with Neuromuscular Electrical Stimulation Leads to Functional Gains in Ambulation in Patients with Secondary Progressive and Primary Progressive Multiple Sclerosis: A Case Series Report. The Journal of Alternative and Complementary Medicine. 2010.
5. Szecsi et al. Functional Electrical Stimulation-Assisted Cycling of Patients with Multiple Sclerosis: Biomechanical and Functional Outcome: A Pilot Study. Journal of Rehabilitative Medicine. 2009.
6. Mills, P., Dossa, F. Transcutaneous Electrical Nerve Stimulation for Management of Limb Spasticity: A Systematic Review. American Journal of Physical Medicine and Rehabilitation. 2016.
7. Meseguer-Henarejos AB, Sanchez-Meca J, Lopez-Pina JA, Carles-Hernandez R. Inter- and intra-rater reliability of the Modified Ashworth Scale: a systematic review and meta-analysis. European journal of physical and rehabilitation medicine. 2018 Aug;54(4):576-90.
8. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6278623/

The quantitative evaluation method of spasticity (Table 1) are significant both for the treatment plan and for the measurement of response to treatment.

9. Neubie: A New Paradigm in Electrical Stimulation. (https://files.constantcontact.com/24512df0601/0849a8cb-57ba-46ff-a620-8d25d3873042.pdf) Garrett Salpeter.

10. Robinson A, Snyder-Mackler L. Clinical Electorphysiologiy: Electrotherapy and Electrophysiologic Testing: Third Edition. In: Stackhouse, S. *Electrical Stimulation of Muscle for Control of Movement and Posture.* Philadelphia, PA: Wolters Kluwer and Lippincott Williams and Wilkins; 2008: 260-262.