TITLE	Effect of Neuro20 Functional Electrical Stimulation Suit on Autonomic Function, Muscle Performance, and Gait
SHORT TITLE	Neuro20
PROTOCOL NO.	0083882
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Brief Overview

We are proposing a 20-participant multi-group case series to examine the effects of the Neuro20 stimulation suit in the amputee and neurologic populations. Our primary aim is to examine the effects of the Neuro20 stimulation suit on walking outcomes. We hypothesize that the Neuro20 suit will improve gait kinematics, gait speed, and muscle performance. Our secondary aim is to examine the mechanisms of the neurologic response to training in the Neuro20 stimulation suit by examining the effects on autonomic function. The Neuro20 assessments and interventions will take place at the Brooks Rehabilitation Clinical Research Center. We propose interventions to include up to 12 sessions with the Neuro20 suit under direct supervision from study staff. Assessments will occur pre-intervention, mid-intervention, and post-intervention.

Section 1: Procedures

1.1 Screening/Recruitment Procedures

Potential participants may be identified by healthcare staff who are part of their normal clinical care or research staff. Potential participants may also hear about the study by word of mouth or by witnessing exercise sessions with Neuro20 suit at Brooks Rehabilitation.

1.1.1 Inclusion/Exclusion Criteria

Inclusion Criteria

- At least one week post amputation or neurologic injury (i.e. brain injury, stroke, spinal cord injury) and deemed medically stable to participate in rehabilitation
- Able to provide Informed Consent by demonstrating the ability to follow a three step command

Exclusion Criteria

- Pacemaker / Defibrillator or severe cardiac disease (Class IV according to New York Heart Association Functional Classification)
- Implanted medical devices
- Active DVT/thrombophlebitis
- Active Cancer
- Active fever, infection, or acute inflammation
- Pregnancy
- Epilepsy or uncontrolled seizures or seizure within the last 6 months
- Implanted stimulator or pump that cannot be turned off externally
- Significant, active wounds in areas stimulated by the suit
- Inability to follow a three-step motor command
- Bleeding tendency

1.2 Informed Consent Process

Informed consent will be obtained by approved study staff in a quiet area to allow for answering of all questions.

- Participant must be able to provide consent
    - Must give accurate yes/no responses
- This study does not allow consent to be provided by a legally authorized representative (LAR)

1.3 Assessments

Participants will complete pre-, mid-, and post-intervention assessments lasting no more than four hours each. Assessments may include any of the following:

Primary Aim Assessments (Gait and Muscle Performance)

- Gait kinematics
- Functional near-infrared spectroscopy during gait
- Clinical gait outcome measures
    - 10-meter walk test
    - Timed up-and-go
    - 6-minute walk test
- Clinical measures of muscle performance
    - 5-time sit-to-stand
    - Muscle strength testing
    - Range of motion measurements

Secondary Aim Assessments (Autonomic Function)

- H reflex measurement
- Clinical spasticity assessments
- Pupillometry
- Heart rate variability

Questionnaires

- Demographic information
- Injury and function classification
- EuroQoL 5D-5L (quality of life)
- Neuro-QoL (quality of life)
- Diagnosis specific participation scale

1.4 Intervention

All interventions will occur at Brooks Rehabilitation. Each participant will complete up to 12 sessions (no more than 3x a week in frequency) under the direct supervision of study staff. We have outlined a potential 60 to 90-minute protocol utilizing several modes of the Neuro20 suit.

Modes:

- **Strength** – this is to be primarily used with strength training exercises or task specific training.
- **Conditioning** – this is to be primarily used to increase parasympathetic autonomic control and to condition the individual to Neuro20 stimulation.
- **Cool Down** – this is to be primarily used at the end of sessions as an active recovery.
- **Massage** – this is to be primarily used for muscle pumping and circulation.
- **Patterned Movements** – this is to be primarily used for improved muscle performance within task specific training.

Operating Mode	Stimulation (Work) Period		Rest Period	
Strength	84 Hz	175 µs	*No stimulation*	*No stimulation*
Conditioning	40 Hz	175 µs	7 Hz	175 µs
Cool Down	100 Hz	75 µs	*No stimulation*	*No stimulation*
Massage	84 Hz	175 µs	7 Hz	175 µs
PEMS - Patterned Movements (all)	84 Hz	175 µs	*No Stimulation*	*No Stimulation*

Protocol Example:

- Conditioning: 20 minutes in supine to patient tolerance with monitoring of symptoms and vitals.
- Strength: 10 minutes of stimulation to abdominals, back extensors, and hip extensors while participant performs bridging in supine.
- Patterned Movements: 30 minutes of gait training with suit during task specific training.
- Cool Down – 10 minutes in supine for active recovery.

Progression:
Because the sample population will be heterogeneous, the protocol will differ between participants. Stimulation time, intensity, and mode will be driven by the response to the intervention rather than a standardized progression. All will receive at least 20 minutes of conditioning as a warm up for at least the first session, strengthening and patterned movements as indicated, and a cool down. Progression will include less time in conditioning and more time in strengthening/patterned movement. Strengthening/patterned movement will be performed with task specific training. Fatigue, quality of movement, and patient symptoms will be monitored throughout and adjustments to stimulation time, intensity, and mode made accordingly.

1.5 Data Analysis

Data will be captured during pre-intervention, mid-intervention, and post-intervention assessments. Data will be compared against normative values when available and change scores from pre-, mid-, and post-testing will be calculated for absolute differences. Questionnaire data will be similarly analyzed except where individual responses cannot be summed as part of a total score such as in the Euro-QOL.

Section 2: Risk Information

2.1 Risks, Side Effects, and/or Discomforts

There are minimal risks to participating in this study. The participants may feel some muscle soreness consistent with exercise within the rehabilitation setting. They may also have minor skin irritation from using the device, which will be monitored. While using the Neuro20 suit, participants may experience tingling or burning sensations or muscle contractions in the muscles and skin under the pads. There is also risk of abnormal heart rate and blood pressure responses. Blood pressure and heart rate will be monitored every 20 minutes of stimulation and with any patient reports of cardiac related symptoms (lightheadedness, dizziness, headache, hot flashes, shortness of breath, etc.). All symptoms will be monitored by study staff and adjusted immediately to participant comfort.

As many individuals with neurologic injury demonstrate limitations in sensation, impaired sensation is not an exclusion criterion, but skin integrity will be closely monitored after each use.

While we believe the risk of injury during this study is minimal, please be advised that Brooks Rehabilitation will manage the participant's care consistent with the management of all treatment-related adverse events. The participant's insurance will be responsible for any medical cost including deductibles, co-insurance, or co-payments. Any injury requiring medical care will be reported to the Institutional Review Board providing oversight of this study.

2.2 Alternatives to Participation

This study is for research purposes only. The alternative is to not participate in this study. By choosing not to participate, your care will not be altered in any way.

2.3 Cost

There is not any monetary compensation for your participation in this study.

Section 3: Monitoring/Reporting of AE/SAE

Records of participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, they will be de-identified.

Participant vitals, skin integrity, and comfort will be monitored by study staff throughout use of the stimulation suit. Any abnormal or adverse responses to wearing of the stimulation suit will be reported to the study physician who will provide medical recommendations for proceeding or terminating use of the suit for the session. Repeated and unresolved abnormal responses will result in withdrawal from the study under the advisement of the study physician. All adverse events will be tracked and reported to the IRB, primary investigator, and study physician.

Section 4: Study Oversight

The Brooks Vice President for Clinical Integration and Research will serve as the principal investigator and maintain administrative oversight of this study, ensuring compliance with this protocol, related policies and procedures of Brooks Rehabilitation and the Brooks Rehabilitation Clinical Research Center, and relevant rules and regulations. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health and welfare of participants. All study documents and procedures will be made available for monitoring, auditing, IRB review and regulatory inspection as required by the IRB and/or by law. The study will be discontinued if the principal investigator, the BRCRC, or the IRB determines necessary. The principal investigator will promptly inform the IRB and provide the reason(s) for the termination or suspension of the study. Circumstances that may warrant termination include, but are not limited to:

- Determination of unexpected, significant or unacceptable risks to participants.
- Insufficient adherence to protocol requirements.
- Data that is not sufficiently complete and/or evaluable.
- Determination of futility.

The principal investigator may terminate a participants' participation in the study if:

- Any situation occurs such that continued participation in the study would not be in the best interest of the participant.

Section 5: Data Management

Data will be collected and stored on a HIPAA-compliant, encrypted, password-protected server at Brooks Rehabilitation that is only accessible to BRCRC authorized personnel. Paper copies will be kept in a locked storage cabinet within the Brooks Rehabilitation Clinical Research Center.