**Influence of Whole Body Vibration on Neuromodulation of Ankle Muscles in Persons with SCI**

**Overall Study Standard Operating Procedure**

**Protocol # 1370226-7**

**Principal Investigator**

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Kyle Condon, DPT

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**General Info**

***Funding***

Funded by NIH NICHD to Shepherd Center, Jasmine Hope, BS F31HD101151

Protocol and Grant prepared by Jasmine Hope, BS and Edelle Field-Fote PT, PhD, FAPTA

***Clinical Trials***

ClinicalTrials.gov ID: NCT04238013

Overall Status: Recruiting

***IRB***

Approval Number 777

Shepherd Center Research Review Committee

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***Study question***

Whether changes in ankle control and spasticity after robust afferent stimulation are due more to corticospinal drive to the tibialis anterior (TA) or reflex modulation of the soleus (SOL).

***Participants***

14 persons with spinal cord injury (SCI)

18-85 years of age

SCI level T12 or above ( ≥ 6 months since injury)

Motor-incomplete classification (AIS C or D)

Self-reported spasticity in at least one ankle

Score of at least 2 on Spinal Cord Assessment Tool for Spastic Reflexes (SCATS) clonus test in at least one ankle (required for enrollment)

Be able to stand and take at least 4 steps with or without assistive devices (BUT NO AFOs during walking tests)

***Study days***

2 full study days (7 hours each, with 1 hour lunch break) or 4 half days (3 hours each)

Table

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***Data Collection Order of Events***

**Pre-Study:**

Consent

SCATS

XSENS Measurements

Cap Head measurements

Determine target leg (most spastic and able to volitionally activate)

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| --- |
| **Session Example** |
| Electrophysiological Testing (CST or SRC) |
| Ankle Strength |
| Ankle Tapping Task |
| Ankle Drop Test |
| 10MWT |
| HR |
| **Intervention (Control)** |
| HR |
| Electrophysiological Testing (CST or SRC) |
| Ankle Strength |
| Ankle Tapping Task |
| Ankle Drop Test |
| 10MWT |

**Session:**

**Study Team Roles**

***Primary Team***

Jasmine Hope, BS, PhD Candidate: Research Coordinator

Jennifer Iddings, PhD: Research Scientist

Cazmon Suri, MS: Biomedical Engineer

Kyle Condon, DPT: Clinical Research Fellow

***Secondary Team***

Anastasia Zarkou, PT, PhD: Postdoctoral Fellow

Allison McIntyre, MOT,OT/L, CCRP: Clinician

***Jasmine Hope, BS, PhD Candidate***

Recruit and Consent Study Participants

Data Collection (ALL)

Data Analysis

Regulatory Documentation

Grant Coordination

Results Dissemination

PhD Dissertation

***Cazmon Suri, MS***

Equipment Setup

Data Collection (XSENS and TMS)

MATLAB Data Analysis

***Jennifer Iddings, PhD (Anastasia Zarkou, PT, PhD)***

Data Collection (H-reflex and TMS)

Study Consultation

***Kyle Condon, DPT (Allison McIntyre, MOT,OT/L, CCRP)***

SCATS

Participant Safety (transfers and walks)

SCISET questionnaire

Data Collection (strength, tapping, drop test, 10MWT)

Intervention (Electrical Stim and WBV)

**Electrophysiological Testing**

During 2 study sessions, we will measure **corticospinal tract (CST)** descending drive using motor evoked potentials using transcranial magnetic stimulation (TMS).

During the remaining 2 sessions, we will assess **spinal reflex circuit (SRC)** modulation using paired pulse stimulation of the tibial nerve. The order of the testing will be determined using a randomization setup in the Redcap form.

Electrophysiological testing will take place before and after each intervention.

During the 1st study session, the SCISET questionnaire will be given by the therapist.

***CST***

**Jasmine:** Cap measurements (pre-study), Electrode prep (including marking electrode position), TMS coil

**Jennifer (Anastasia):** Record cap measurements and TMS notes in data sheet and (Jasmine will transfer data to Redcap post-collection), Run PEST and Signal

**Cazmon:** TMS triggers and MVC monitoring via Spike

**Kyle (Allison):** Transfer participant to and from bed

Protocol:

* Measure and Prep Participant: target leg TA and SOL
* Record Maximum Voluntary Contraction using RMS filter (have Spike up)
* Find Hotspot (TA)
* Find Active Motor Threshold via PEST and confirm with 5/10 trials at 100uV (with baseline subtraction) during 10-15% MVC TA
* 80% MSO – 10 stimuli
* 120% AMT – 10 stimuli
* 100% MSO ­­­– 10 stimuli

***SRC***

**Jasmine:** Electrode prep (including marking electrode position), Digitimer stim

**Jennifer(Anastasia):** Run Spike and Signal and record in excel

**Kyle(Allison):** Transfer participant to and from bed

Protocol:

* Prep Participant: target leg TA and SOL
* H/M recruitment curve SOL
* Calculate H wave @ 10-15% Mmax
* Determine stimulation intensity
* 10 paired pulse trains (10 seconds between each train)

**Ankle Control and Spasticity Testing**

***Ankle Strength***

**Jasmine:** Record dynamometer output in data sheet, (Jasmine will transfer data to Redcap post-collection)

**Kyle(Allison):** Transfer participant to small hi-low mat, instruct participant to dorsiflex against dynamometer

Protocol:

* Transfer participant to hi-low mat
* Place foot against dynamometer
* 3, 3s trials for target ankle, 60 s rest in between

***Ankle Tapping Task***

**Jasmine:** Record number of taps in data sheet, (Jasmine will transfer data to Redcap post-collection)

**Kyle (Allison):** Use stopwatch, help put on XSENS markers

**Cazmon:** Run XSENS and set up speakers

Protocol:

* Place Xsens for lower extremities
* Attach tapping apparatus to speakers
* 4, 10s trials for target ankle, 60 s rest in between

***Ankle Drop Test***

**Jasmine:** Measurements, Hold and drop leg

**Kyle (Allison):** Hold T-bar, record measurements in data sheet, (Jasmine will transfer data to Redcap post-collection)

**Cazmon:** Run XSENS

Protocol:

* Measure 90 degree knee angle, knee to mat, mat height, and 10cm above resting knee
* 3, trials for target ankle, 60s rest in between

***10MWT***

**Jasmine:** Time walks, record in data sheet, (Jasmine will transfer data to Redcap post-collection)

**Kyle (Allison):** Guard participant

**Cazmon:** Run XSENS

Protocol:

* Walk out to hallway, bring out a chair
* 3, 10MWT, 2mins rest in between

**Intervention**

***Electrical Stimulation (Control) Treatment (AM Testing)***

**Kyle (Allison):** Guard participant and transfer

Protocol:

* Record heartrate
* Place 2 Empi electrodes on back
* Turn on Empi until participant can detect, then ramp down subthreshold, then turn off(keep participant masked from seeing Empi)
* 8 bouts of 45s stand, 1min rest
* Record heartrate

***Whole Body Vibration (WBV) treatment (PM Testing)***

**Kyle (Allison):** Guard participant and transfer

* Record heartrate
* Set WBV platform to 50hz high amplitude
* 8 bouts of 45s vibration, 1min rest
* Record heartrate