

# Can exercise combined with Cranial Nerve Non-Invasive Neuromodulation (CN-NINM) Improve Mobility in Non-Ambulatory People with MS? A case study series Georgia Corner, DPT, Janet Ruhland, PT, MA, Mitchell Tyler, PE, MS, Yuri Danilov, PhD, Kimberly Skinner, MPT

Background: Though there is a growing body of evidence supporting rehabilitation for people with MS, there is a scarcity of literature regarding effective interventions for people in the advanced stages of the disease. This case study series presents an innovative intervention that combines targeted physical therapy for movement control with a neuromodulation device. The resultant motor learning has the potential to improve functional mobility in people with advanced symptoms of MS.

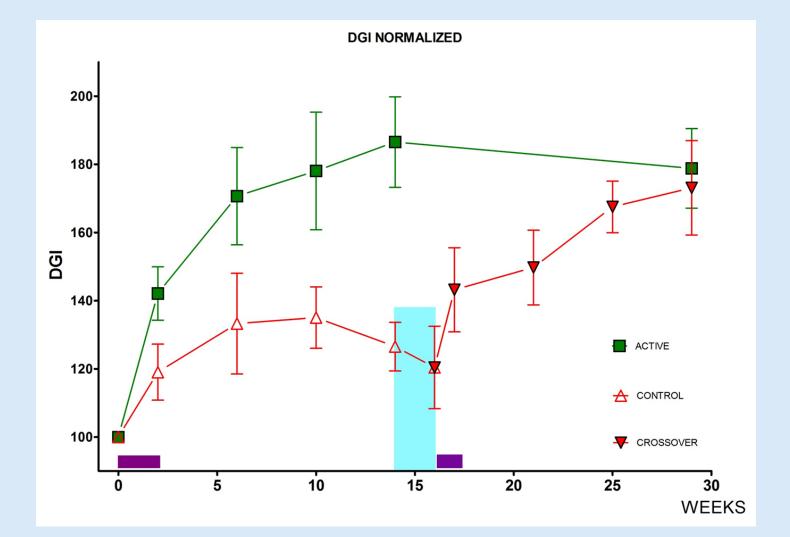
**Objectives:** Pilot study to determine if the CN-NINM intervention can improve balance, gait, and mobility in subjects with advanced MS; to identify performance measures that are responsive in this population.

**Participants:** 6 subjects (EDSS 6.5-7.5) participated.

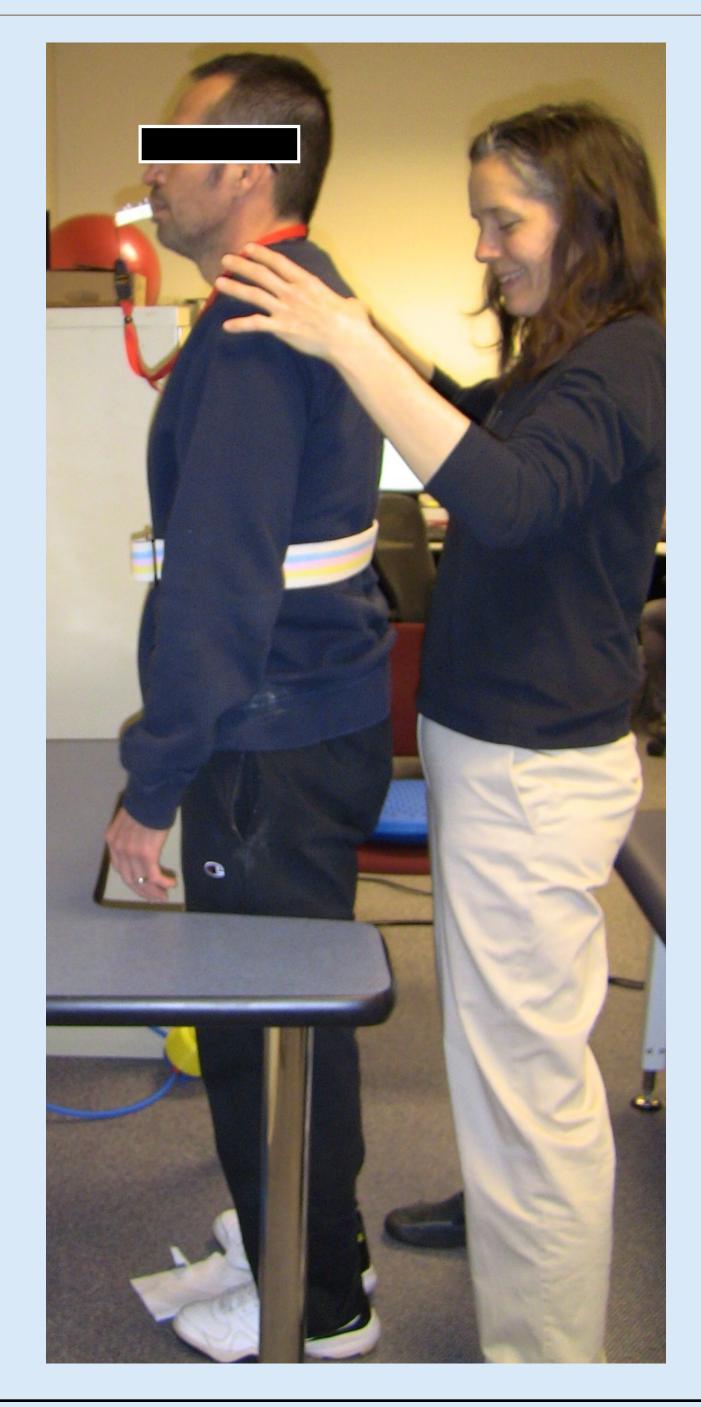
Outcomes: Trunk Impairment Scale (TIS), Multiple Sclerosis Impact Scale (MSIS-29), Modified Fatigue Impact Scale (MFIS), 12-item MS Walking Scale (MSWS), Impact of Visual Impairment Scale (IVIS), and Box & Blocks, Repeatable Battery for the Assessment of Neuropsychological Status (RBANS), video nystagmography. If applicable: Medical Outcomes Study Pain Effects Scale (PES), Bladder Control Scale (BCS), Bowel Control Scale (BWS), Walking Distance and Speed, Static Standing Balance Test, Gross Motor Function Measure (GMFM), and Modified Rivermead Mobility Index (MRMI).

#### Why the tongue?

- Sensory stimulation projects to the brainstem,
- specifically the solitary and trigeminal nuclei, via
- Cranial Nerves V and VII.
- High density of sensory nerve endings Saliva is excellent electrolyte
- Tongue stays at constant pH+ and t<sup>o</sup>
- Electrode array is non-invasive
- Discreet protected environment
- Comfortable sensation

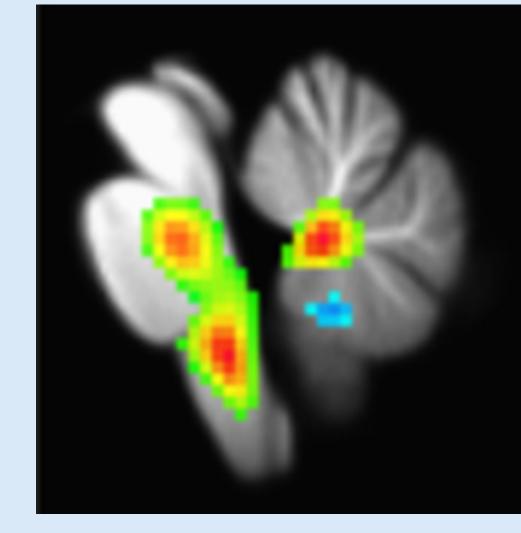


Previous results in ambulatory people with MS.





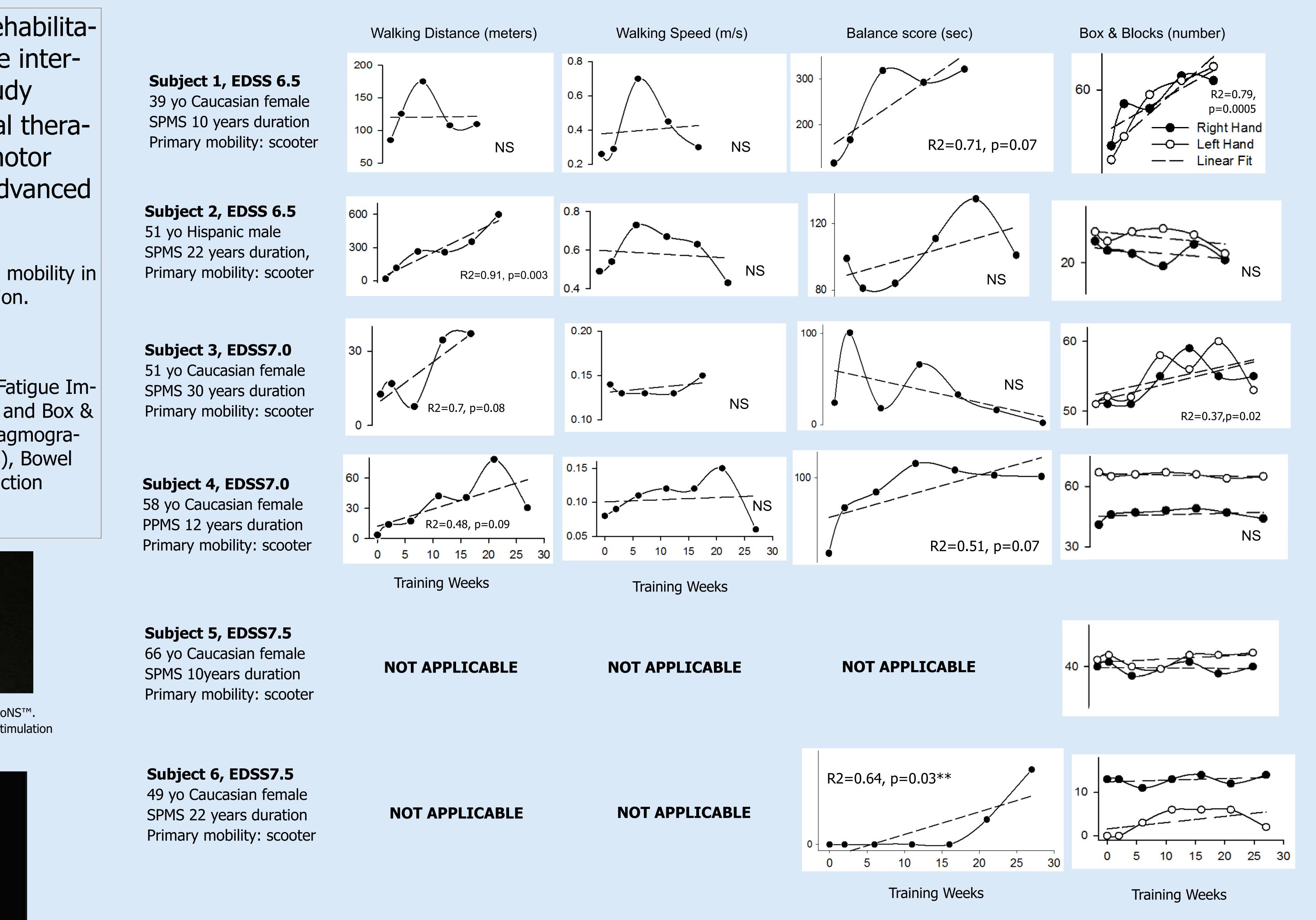
Portable Neuromodulation Stimulator PoNS The PoNS provides a gentle electrical stimulation to the tongue.



our fMRI study with subjects who have balance ficits due to primary vestibular dysfunction, trauprain injury, and spinocerebellar ataxia, the in reated changes in localized brain activity levels, corresponding to improved balance, gait, mood, and sense of well-being.

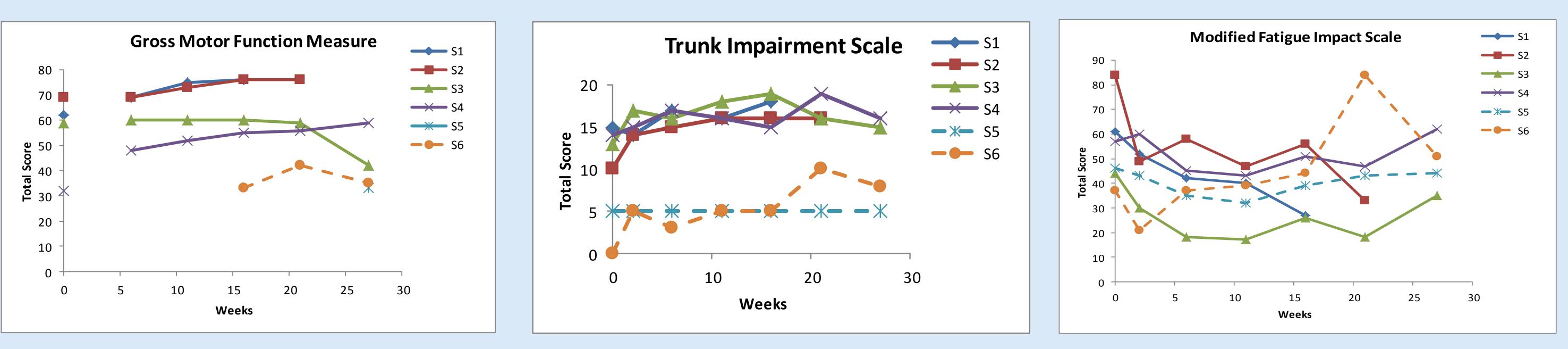
**Intervention:** AM: brief warmups, 20 minutes balance, 20 minutes gait, 20 minutes breathing and relaxation (all with PoNS) PM: 20 minutes balance, 20 minutes gait, movement exercises. The training template was customized to meet the needs of each individual. The program was progressed as individuals improved in order to keep their training in their "sweet spot."

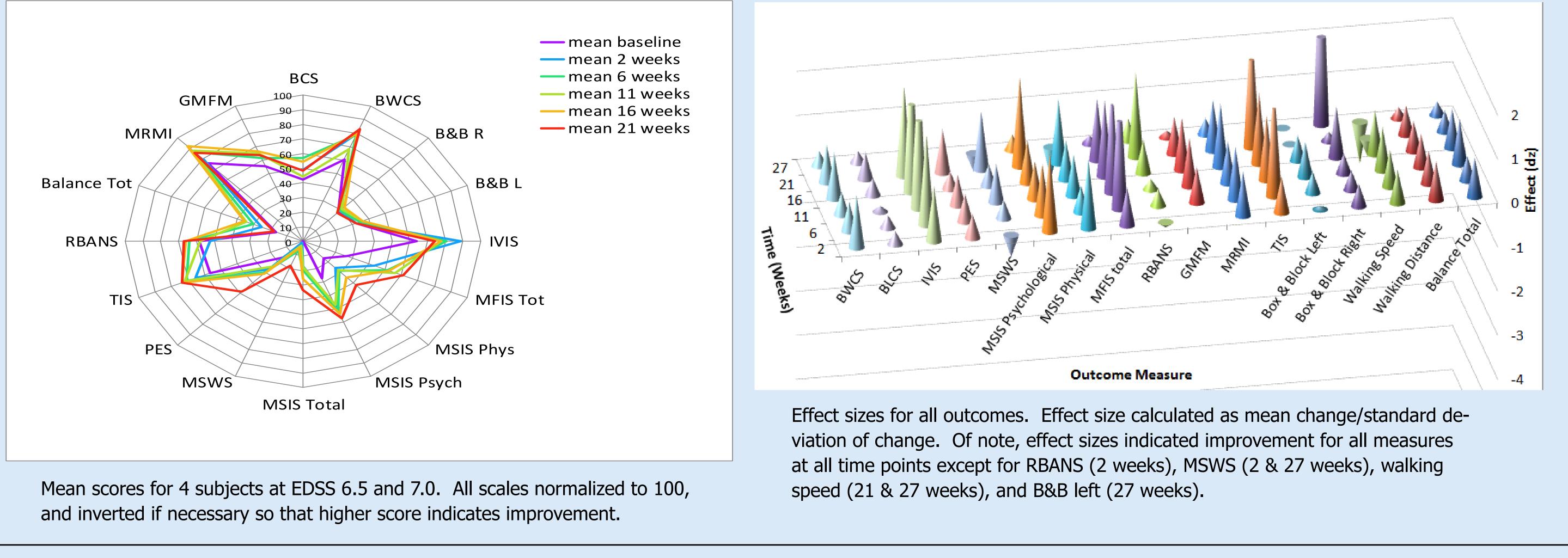
Subjects were tested at baseline; trained for 2 weeks in the lab, followed by 5 cycles of 4 weeks home training/1 week in-lab training and testing. Total intervention 6 months.



**Results:** All subjects tolerated the intervention, with average home program compliance of >80% and no adverse events attributable to study participation. Three of the 4 subjects with EDSS 6.5 – 7.0 improved their walking speed and/or distance, MFIS, and MSIS-29 scores. Subjects with EDSS 7.5 showed limited gains, but tolerated the physical activity of the protocol without adverse event. The demanding CN-NINM regimen also resulted in significant real life improvements: increased walking speed, re-adopting a walker for community mobility, overcoming physical obstacles at home to increase community access, decreased falls, decreased pain and parasthesias.

Abbreviations used: SPMS, Secondary Progressive Multiple Sclerosis; EDSS, Extended Disability Status Scale; PPMS, Primary Progressive Multiple Sclerosis. Disclosure: authors Tyler and Danilov have an ownership interest in NeuroHabilitation Corporation (NHC), which is commercializing the technology. This work was supported by the University of Wisconsin Foundation.





## **Conclusions:**

- subjects.
- community access.
- EDSS 6.5 and 7.0
- ment module modification.



### **Aggregate data—EDSS 6.5 and 7.0**

### Despite the rigorous training regimen, fatigue improved or remained unchanged in all

. Subjects at EDSS 6.5 and 7.0 made the most significant gains. These included functional improvements such as increased mobility with less restrictive devices and increased

. Trend was toward improvement in all measures, when looking at aggregate results for

. This intervention may not be appropriate for those at EDSS 7.5, at least without treat-

.A controlled study, with more mobile subjects (EDSS 6.5–7.0) could tease out the contributions of stimulation and exercise to changes in mobility.